Exhibit E

Confidential

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVNIA

UNITED STATES OF AMERICA, CALIFORNIA, ILLINOIS, NEW JERSEY, NEW YORK and TEXAS *ex rel.* CHRIS PURCELL and KIMBERLY GROOME Plaintiffs, v. GILEAD SCIENCES, INC. Defendant.	Case No. 2:17-cv-3523-MAK

EXPERT REPORT OF DR. ANUPAM B. JENA, MD, PhD

May 3, 2021

TABLE OF CONTENTS

I. INTRODUCTION

A. Qualifications

1. I am the Ruth L. Newhouse Associate Professor of Health Care Policy and Medicine at Harvard Medical School and a physician in the Department of Medicine at Massachusetts General Hospital ("MGH"), Harvard Medical School's largest affiliated teaching hospital. I earned my M.D., and Ph.D. in Economics, from the University of Chicago, and my Bachelors in Biology and Economics from the Massachusetts Institute of Technology.

2. As a physician, I work as an Internal Medicine Specialist treating patients in the hospital. I treat a wide variety of acute and chronic general medical conditions, including patients with acute and chronic hepatitis due to viral hepatitis (including Hepatitis B ("HBV")) as well as patients with progressive and end-stage liver disease of other etiologies and hepatocellular carcinoma. In my clinical practice I prescribe a broad range of pharmacologic and other therapies and am familiar with how clinical decisions are made regarding treatment.

3. As an economist, I specialize in the economics of physician behavior, the economics of health care productivity, and the economics of medical innovation. I am also a faculty research fellow at the National Bureau of Economic Research, the nation's leading nonprofit economic research organization. I have published approximately 150 peer-reviewed articles in leading medical and economics journals, including the *New England Journal of Medicine*, *Journal of the American Medical Association*, *British Medical Journal*, *Journal of Health Economics*, *Journal of Public Economics*, and *Journal of Economic Perspectives*. From 2014 to 2015, I served on the Institute of Medicine ("IOM") Committee on Diagnostic Errors in Health Care, which was tasked with preparing a follow-on report to the previous highly influential IOM reports, *To Err is Human* and *Crossing the Quality Chasm*. The 2015 report focused on the epidemiology, causes, and policy solutions for diagnostic errors in medicine. In

2016 and 2018, I served on the Centers for Medicare and Medicaid Services ("CMS") Technical Expert Panel for episode-based resource use measures, which provided advice to CMS on how to design pay-for-performance measures for individual physicians based on their costs of care when treating patients. Since 2018, I have served on the Advisory Committee on Emerging Science, Technology, and Innovation for the National Academy of Medicine (formerly, the Institute of Medicine). In 2020, I served on the National Academy of Medicine Committee on the Implications of Discarded Weight-Based Drugs. In addition to my academic research, I have consulted for the government, the insurance industry, and pharmaceutical firms on issues related to the economics of pharmaceutical innovation.

4. In 2007, I was awarded the Eugene Garfield Award by Research America for my work demonstrating the economic value of medical innovation in HIV/AIDS. In 2013, I received the National Institutes of Health Director's Early Independence Award to fund research on the physician determinants of health care spending, quality, and patient outcomes. In 2015, I was awarded the International Society for Pharmacoeconomics and Outcomes Research New Investigator Award. I have lectured internationally and was named one of the 60 Most Powerful People in Health Care in 2016 and one of the 100 Great Leaders in Health Care in 2018 by *Becker's Hospital Review*. My research and scholarly opinions have been published in the New York Times, Washington Post, Wall Street Journal, Harvard Business Review, and other places.

5. My curriculum vitae is attached as **Appendix A**. A list of my testimony in the last four years is contained in **Appendix B**.

B. Relators' Allegations

6. Relators allege that Defendant Gilead Sciences, Inc. ("Gilead") ran a "pay for play scheme,"[1] covering the period from "as early as 2013 and continuing to the present, [over which] Gilead has paid tens of thousands of dollars in the form of speaker honoraria, destination trips, meals and beverages and other in-kind benefits for the purpose of inducing [Healthcare Professionals ("HCPs")] to prescribe Gilead [HBV] drugs."[2] Relators specifically focus on Gilead's Opinion Leader Program ("OLP"), which "consisted of Advisory Boards ("Ad Boards") and Speaker Programs."[3]

7. Relators further allege that "Gilead knew, or should have known, that its unlawful activities would cause HCPs to routinely file false claims for reimbursement from the federal and state governments in violation of the [False Claims Act] and state and local laws, the federal Anti-Kickback Statutes… and similar state laws."[4]

C. Overview and Assignment

8. I have been asked by counsel for Gilead to review and assess the allegations that Gilead's OLP constituted a "pay for play scheme."

9. First, I have been asked to assess the specific marketing strategies that Gilead used for its HBV drugs, Viread® and Vemlidy®, including whether Gilead's speaker programs and advisory boards served a legitimate purpose and were consistent with industry practice.

---

1 Fourth Amended Complaint at ¶ 2, *United States of America, et al., ex rel. Purcell v. Gilead Science, Inc.*, No. 17-cv-3523 (E.D. Pa. Sept. 30, 2020), ECF No. 117 (hereinafter, "Complaint").

2 Complaint, ¶ 3.

3 Complaint, ¶ 4.

4 Complaint, ¶ 12.

10. Second, I have been asked to assess whether Gilead's speaker and advisory board programs were consistent with the guidelines of the Office of Inspector General for the Department of Health and Human Services ("OIG"), or otherwise bore indicators of "sham" events designed to induce prescriptions of Viread® and Vemlidy®, including whether the payments Gilead provided to the physicians that served as speakers or advisors at those programs exceeded the fair market value of the services rendered.

11. Third, and finally, I have been asked to determine if there is evidence that payments for speaker and advisory board programs may have impacted physician prescribing of Viread® and Vemlidy®.

12. This report and the opinions expressed herein are based on my analysis of the information and materials available to me as of the date of this report, as well as my training in medicine and health economics. To the extent I rely on my medical training and clinical experience to reach any opinions expressed in this report, I hold those opinions to a reasonable degree of medical certainty. Similarly, I hold my economic-related opinions to a reasonable degree of professional certainty in the field of economics. I reserve the right to amend or supplement this report in the event that new information relevant to my opinions is produced in this case. A list of the materials that I relied on is included in **Appendix C**.

13. Under my direction, Analysis Group, Inc. performed some of the work for this report. I am being compensated for my work in this case at the rate of $950 per hour. In addition, I receive a portion of the fees paid to Analysis Group, Inc. for its work. This compensation is not contingent on the nature of my findings or the outcome of this litigation.

II. SUMMARY OF CONCLUSIONS

14. My review of the available data and documents related to Gilead's HBV speaker and advisory board programing indicates that they were consistent with the government's OIG

guidelines and industry standards at the time, aimed at ensuring the beneficial aspects of such programs, and did not demonstrate characteristics associated with improper influence on physician prescribing. Below is a high-level summary of my findings.

15. *First*, I have determined that Gilead's marketing strategy reflected industry practice, and its speaker and advisory programs served legitimate and societally beneficial purposes. Speaker programs and advisory boards are common components of pharmaceutical marketing strategies, and it is widely recognized that both can provide significant benefits to patient care. For example, speaker programs can help disseminate important information and improve patient treatment. Advisory boards can provide critical feedback to pharmaceutical companies about patient treatment, drug side effects, insurance coverage, and other data points that pharmaceutical companies then incorporate into their marketing strategies to improve messaging and, ultimately, treatment outcomes.

16. Gilead documents indicate that the purpose of its speaker programs was to support the brand with materials designed to educate and inform physicians and other healthcare professionals (HCPs) who are part of the continuum of patient care. Similarly, advisory boards provided an opportunity for Gilead to better understand real-world safety and efficacy concerns related to Viread® and Vemlidy®, barriers to HBV diagnosis and treatment (for example, access to testing, stigma, and cost), and patient perceptions. Gilead documents offer insight into the information that was collected during Viread® and Vemlidy® advisory board programs, and the fact that future marketing materials and clinical trial designs often reflect the advisors' feedback.

17. *Second*, I conclude that neither Gilead's HBV speaker nor advisory board programs bore indicators of "sham" programs, designed to improperly influence physician prescribing. Gilead's Business Conduct Manuals outlined internal policies that were remarkably

similar to the OIG guidelines, and my review of the available data and documents indicates that Gilead's programs complied with these rules. More specifically, my findings are that: (1) Gilead's payments to physicians for speaker and advisory board programs generally reflected a fair market value; (2) Gilead's methodology to calculate these payments had a reasonable economic basis, was transparent, and was based on objective data; (3) Gilead's speakers and advisors had extensive HBV treatment, publication, and teaching experience; (4) Gilead maintained and enforced strict rules regarding the value of meals it provided at speaker and advisory board programs, with 96 percent of programs at or below the spending limit, and exceptions were often a result of fewer than expected attendees at fixed fee venues; notably exceptions were flagged for follow up by Gilead; and (5) Gilead held different types of speaker programs that targeted professional and patient audiences (i.e., professional programs for health care professionals ("HCPs") and community programs for community members), and the vast majority of both types of programs were very well attended and exceeded Gilead's expected attendance requirement. Gilead's advisory boards were similarly well attended and in line with Gilead's rules regarding advisory board attendance.

18. *Third*, I find no evidence that payments to physicians for participating in Gilead's HBV speaker and advisory board programs impacted prescribing of Viread® and Vemlidy®. This supports my prior conclusion as well: If a physician's prescribing is not impacted by the allegedly improper payment, then it calls into question whether that payment was improper. In addition, economic damages would only result to the extent that physician prescribing was affected (i.e., they would have prescribed a clinically substitutable and lower-priced alternative product). The fact that speakers and advisors at Gilead programs were often also high prescribers of HBV drugs does not constitute evidence of an improper influence on prescribing. On the

contrary, physicians with the highest level of prescribing often have the most relevant experience, and thus are best positioned to be able to educate other less-informed or less-experienced physicians, other HCPs, patients, and Gilead (through advisory boards). Indeed, it is entirely consistent with the goal of appropriately disseminating beneficial information on HBV treatment to physicians, other HCPs, and patients for Gilead to have speakers who specialize in the treatment of HBV and who, in many cases, were high prescribers of HBV products.

19. If speaker and advisory board payments improperly influenced a speaker's or advisor's prescribing, then one might expect prescribing to increase when the payments increase (i.e., that payments and prescribing were correlated). Even if such a trend existed, it would not necessarily mean that the increased payments *caused* the increased prescriptions. Introductory economics teaches that correlation is not the same as causation. However, my review of the payment and prescribing data for Viread® and Vemlidy® does not even indicate a general correlation, let alone suggest that payments caused additional prescribing. Indeed, while Gilead's aggregate payments for speaker and advisory board programs fluctuate substantially over time, total Gilead prescriptions remained relatively constant up through the launch of the generic formulation of Viread® in December 2017. Similarly, I find that there is virtually no relationship between changes in payments to individual physicians and changes in prescribing by those physicians, let alone evidence suggesting higher payments caused additional prescribing. Specifically, my correlation analysis yields a correlation coefficient of only 0.08, which suggests no economically meaningful relationship between changes in payments and changes in prescribing.

20. Further, I find that prescribing patterns for individuals who received speaker and advisory board payments were similar to prescribing patterns for those who did not receive such

payments. The lack of relationship between trends in speaker and advisory board payments and Viread® and Vemlidy® prescribing is consistent with my finding that the programs were appropriately designed to ensure that the payments would not influence speaker or advisor prescribing. Overall, these findings are inconsistent with the allegation that the speaker and advisory board payments were kickbacks, and are consistent with a finding that the federal and state governments in this case have not experienced any damages as a result of Gilead speaker and advisory board programs.

III. BACKGROUND

A. Hepatitis B Virus

21. HBV is a chronically underreported and undertreated infectious disease.[5] In 2018, the U.S. Centers for Disease Control and Prevention ("CDC") reported 3,322 cases of acute HBV. But "after adjusting for under-ascertainment and under-reporting," the CDC estimates that "21,600 acute hepatitis B cases occurred in 2018,"[6] which means that approximately 85 percent of HBV cases are unascertained or unreported.[7] As a result, the number of untreated HBV positive individuals at any point in time is likely to exceed the number of diagnosed patients receiving treatment in a given year. HBV, which is frequently asymptomatic in the acute phase,[8]

---

[5] "About Hepatitis B," *UC San Diego Health*, available at https://tinyurl.com/yhfs47v4 ("A chronic hepatitis B infection can go undetected for years – even decades in many cases. The longer a hepatitis B infection is left untreated, the more susceptible you are to developing severe scarring of the liver (cirrhosis) and liver cancer.").

[6] "Hepatitis B Questions and Answers for Health Professionals," *Centers for Disease Control and Prevention*, available at https://www.cdc.gov/hepatitis/hbv/hbvfaq htm#overview.

[7] Other sources report similar figures for the rate of undiagnosed chronic hepatitis B patients (81.4 percent in the U.S.). *See, e.g.,* Ogawa, Eiichi et al., "Diagnosis Rates of Chronic Hepatitis B in Privately Insured Patients in the United States," *Jama Network*, April 9, 2020, available at https://tinyurl.com/yerduv29. *See also*, "Hepatitis B," *World Health Organization*, July 27, 2020, available at https://www.who.int/news-room/fact-sheets/detail/hepatitis-b. (89.5 percent globally).

[8] "Hepatitis B," *World Health Organization*, available at https://www.who.int/ith/diseases/hepatitisB/en/ ("Most acute HBV infections are asymptomatic or cause mild symptoms, which are often unrecognized.").

can become a chronic disease if left undiagnosed and untreated.[9] As of 2016, an estimated 862,000 people in the U.S. were infected with chronic hepatitis B ("CHB").[10]

22. It is well documented that individuals with chronic infectious diseases such as HBV face stigma, which can reduce their "willingness to engage with medical professionals or disclose disease status."[11] This stigma originates from a number of causes, including "preconceptions that a person may use drugs or may be sexually promiscuous as well as irrational fear of contagion, often fueled by a lack of knowledge and understanding of transmission routes for HBV."[12] As discussed further below, failure to treat HBV can lead to more serious (and costly) medical conditions. Events that educate populations impacted by HBV can increase the number of individuals who undergo screening and subsequently seek and receive treatment, reducing transmission to others as well as costs associated with delayed

---

9 "Treatment Options for Hepatitis B," *Hepatitis B Foundation*, available at https://www.hepb.org/treatment-and-management/treatment/. *See also,* Fung, Scott, et al., "Treatment of Chronic Hepatitis B: Who to Treat, What to Use, and For How Long," *Clinical Gastroenterology and Hepatology*, 2004, Vol. 2(10), pp. 839 - 848, at p. 839.

10 "Hepatitis B Basic Information," *Health and Human Services*, available at https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-b-basics/index html.

11 Smith-Palmer, Jayne et al., "Impact of Stigma on People Living with Chronic Hepatitis B," *Patient Related Outcomes Measures*, March 9, 2020, vol. 11, pp. 95 - 107, at p. 95, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7082540/.

12 Smith-Palmer, *supra* note 11, at pp. 96.

treatment (or lack of treatment) and late-stage intervention for those already infected.[13] Exhibit 1 demonstrates that levels of HBV antiviral treatment have risen substantially over the at-issue time period, with total units prescribed increasing by about 26 percent from the beginning of 2013 to the end of 2019.

23. Chronic HBV is associated with substantial health-related and societal costs. Left untreated, HBV can lead to a number of complications, including cirrhosis of the liver, liver failure, or, in the direst of cases, liver cancer (hepatocellular carcinoma), which is almost universally fatal without a liver transplant.[14]Additionally, HBV can cause kidney disease or inflammation of blood vessels.[15] Not only are these conditions harmful to patients, they are associated with much higher costs than treating HBV directly through medication.

24. For example, a 2017 National Academies of Sciences, Engineering, and Medicine study found that if "current diagnosis, care, and treatment practices remain unchanged, as many as 6 percent of the 2015 [chronic HBV] cohort will have developed hepatocellular carcinoma,

---

[13] Shah, Hemant, et al., "Education Provides Significant Benefits to Patients With Hepatitis B Virus or Hepatitis C Virus Infection: A Systematic Review," *Clinical Gastroenterology and Hepatology*, August 2013, Vol. 11(8), pp. 922 - 933, at p. 922, available at https://www.cghjournal.org/article/S1542-3565(13)00584-3/pdf ("Simple educational interventions for patients with HBV or HCV infection significantly increase patients' knowledge about their disease. More complex, multimodal educational interventions seem to cause behavioral changes that increase rates of testing, vaccination (for HBV), and treatment."); *See also*, Juon, Hee-Soon, et al., "Effect of a liver cancer education program on hepatitis B screening among Asian Americans in the Baltimore-Washington metropolitan area, 2009 - 2010," *Preventing Chronic Disease*, Vol. 11, Feb. 6, 2014, available at https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1083&context=sphhs_prev_facpubs ("We tested the effectiveness of a culturally tailored liver cancer education program for increasing screening for HBV among Chinese, Korean, and Vietnamese Americans… Approximately 79% (n=688) of participants completed the 6-month follow-up telephone survey. Among those who had not had HBV screening at baseline (n=446), the adjusted odds of self-reported receipt of HBC screening at the 6-month follow-up to the educational program were significantly higher for the intervention group than for the control group (odds ratio = 5.13…").

[14] Chen, Moon S Jr., et al., "Hepatitis B among Asian Americans: Prevalence, progress, and prospects for control," *World Journal of Gastroenterology*, Vol. 21(42), November 14, 2015, pp. 11924 - 11930, at p. 11924, available at https://www ncbi.nlm.nih.gov/pmc/articles/PMC4641114/.

[15] "Hepatitis B - Symptoms & Causes," *Mayo Clinic*, available at https://www mayoclinic.org/diseases-conditions/hepatitis-b/symptoms-causes/syc-20366802.

10.31 percent will have developed cirrhosis, and 9.40 percent will have died from HBV-related deaths by year 2030." If the current diagnosis rate is doubled (alongside a care and treatment rate of 80 percent), "it would prevent hepatocellular carcinoma, cirrhosis, and HBV-related death by 12, 12.6, and 19 percent, respectively." The study concludes that "[i]ncreasing the cascade of diagnosis, care, and treatment is cost-effective across all the scenarios examined." Notably, this study included treatment with branded Viread® in its cost effectiveness calculation.[16]

25. Similarly, a 2018 study published in the Journal of Hepatology estimated annual costs for Medicare patients with conditions stemming from CHB, including compensated liver disease, decompensated cirrhosis, hepatocellular carcinoma, and liver transplant. In 2015 dollars, the total average annual costs ranged from $69,107 for compensated liver disease, to $184,215 for decompensated cirrhosis.[17] In the same year, the gross Medicare cost (i.e., not accounting for rebates) for a year of Viread® treatment was just over $11,000. And in 2016, the cost for Vemlidy® was approximately $14,000 - both substantially lower than the annual estimated costs to treat conditions stemming from CHB.[18]

---

[16] Toy, Mehlika, "Appendix A Population Health Impact and Cost-Effectiveness of Chronic Hepatitis B Diagnosis, Care, and Treatment in the United States," *National Academies Press (US)*, March 2018, 2017, available at https://www ncbi.nlm.nih.gov/books/NBK442231/.

[17] Nguyen, Mindie, et al., "Healthcare resource utilization and costs by disease severity in an insured national sample of US patients with chronic hepatitis B," *Journal of Hepatology*, October 1, 2019, Vol. 70, pp. 24 - 32, at pp. 25, 28, available at https://www.sciencedirect.com/science/article/pii/S0168827818324401. Estimated costs based on patients adult patients with "≥1 inpatient or ≥2 outpatient non-rule-out medical claims (on different days and at least 30 days apart) with a diagnosis of CHB (ICD-9-CM diagnosis codes 070.22. 070.23, 070.32, 070.33, 070.30 or 070.31) in any diagnostic position between January 1, 2004, and June 30, 2015." While other report average costs associated with these conditions, I was unable to locate additions studies that specifically calculate *Medicare* costs.

[18] Medicare Part D Dashboard data, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD. To determine the cost for a year of treatment, I multiplied the "Average Spending Per Claim" by 12, assuming patients will have one fill (or Claim) per month.

26. Furthermore, HBV disproportionately affects Asian Americans, with one paper estimating that about 58 percent of U.S. cases were amongst individuals who migrated from Asia. Simultaneously, Asian Americans have one of the lowest cancer screening rates, putting them at significantly elevated risk for cancer stemming from HBV.[19] In fact, HBV is considered "the primary risk factor for liver cancer" among this population.[20]

27. During the relevant time period in this case, Gilead marketing materials focused heavily on the undertreated HBV population: nearly half of speaker events were community oriented (i.e., patient-focused) rather than targeted at HCPs. Many of the community oriented events were presented in languages other than English, such as Chinese, Vietnamese, Cambodian, Burmese and Korean.[21] Community speaker programs focused generally on HBV and available treatment options, rather than Gilead's HBV products specifically. Similarly, [redacted] Gilead's professional (i.e., HCP-oriented) speaker programs discussed HBV generally rather than Gilead's HBV products. The specific content and purpose of these programs is discussed in Section IV.

B. Viread® and Vemlidy®

28. HBV is typically treated using antiviral medications, although certain patients may require interferon injections or a liver transplant, depending on age and disease severity.[22] Common antiviral treatments include Viread® (tenofovir disoproxil fumurate ("TDF")),

---

19 Chen, Moon S Jr., *supra* note 14, at p. 11925.

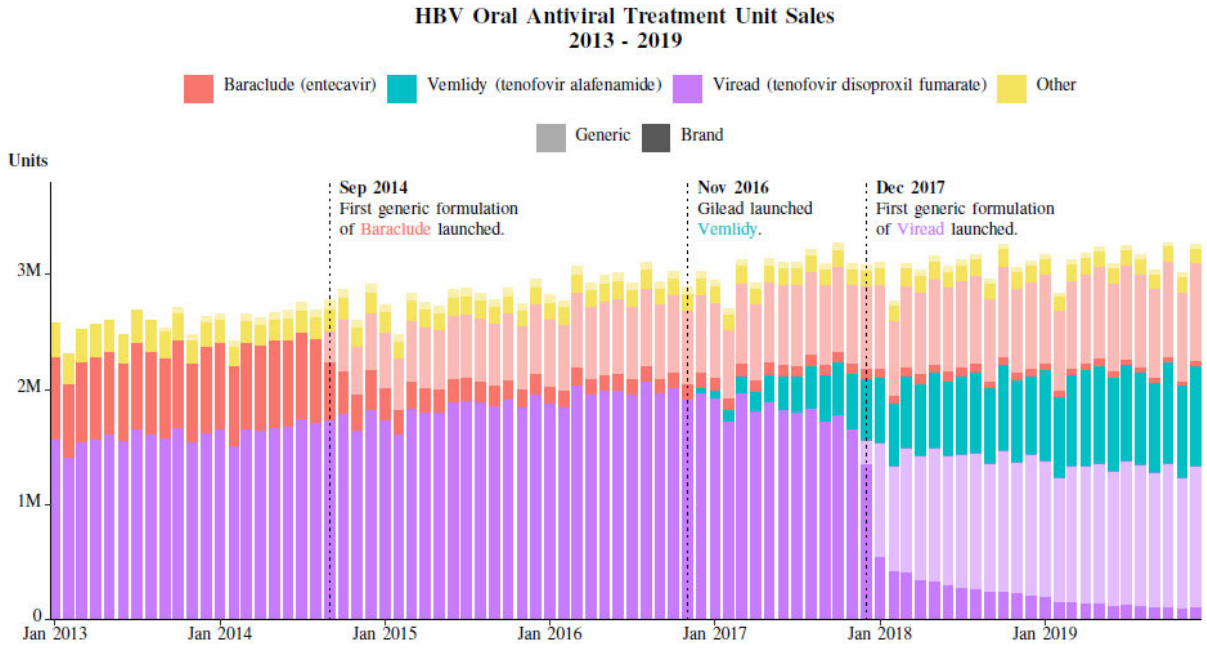
20 "Asian Americans and Cancer," *Rogel Cancer Center, University of Michigan*, available at https://www.rogelcancercenter.org/living-with-cancer/survivorship/advocacy/asian-americans-and-cancer.

21 Gilead_Purcell_00278464, Gilead_Purcell_00134582, Gilead_Purcell_00324518, Gilead_Purcell_00327015 ("Speaker Program Spend Reports").

22 "Hepatitis B - Diagnosis and Treatment" *Mayo Clinic*, September 4, 2020, available at https://www mayoclinic.org/diseases-conditions/hepatitis-b/diagnosis-treatment/drc-20366821.

Vemlidy® (tenofovir alafenamide ("TAF")), Baraclude (entecavir), Epivir (lamivudine), Hepsera® (adefovir), and Tyzeka (telbivudine). Viread®, Vemlidy®, and Baraclude (and the generic formulations, if available) are all considered first-line treatment options, while Epivir, Hepsera®, and Tyzeka (and their generic formulations) are used less frequently.[23] Exhibit 1 provides a summary of the primary antiviral medications over the at-issue time period.

Excerpt of Exhibit 1[24]



29. Viread® (TDF) was approved by the U.S. Food and Drug Administration ("FDA") in 2001 as a treatment for HIV, and received FDA approval for HBV in 2008.[25] Prior to receiving this approval, Hepsera® (adefovir) was Gilead's only product used to treat HBV.

---

[23] Lok, Anna, MD, "Hepatitis B virus: Overview of management," *UpToDate*, July 2, 2019.

[24] The set of drugs included in this analysis is based on HBV treatment guidelines, both from public sources and from documents produced by Gilead. "Other" includes all branded and generic versions of Hepsera® (adefovir dipivoxil), Tyzeka (telbivudine), and Epivir HBV (lamivudine HBV). Symphony Health Data (accessed on March 18, 2021); "Approved Drugs for Adults," *Hepatitis B Foundation*.

[25] "U.S. Food and Drug Administration Approves Viread® for Chronic Hepatitis B in Adults," *Gilead*, August 11, 2008, available at https://www.gilead.com/news-and-press/press-room/press-releases/2008/8/us-food-and-drug-administration-approves-vireadr-for-chronic-hepatitis-b-in-adults.

Because of Viread®'s superior efficacy relative to Hepsera®,[26] Gilead anticipated that Viread® would largely replace Hepsera®.[27] Indeed, by 2013 Hepsera® and generic adefovir prescriptions accounted for under 5 percent of common HBV antivirals, and under 2 percent by 2018. In December 2017, Teva launched a generic form of Viread®.[28]

30. Vemlidy® (TAF) came to the market in November 2016. At its launch, Gilead reported that Vemlidy® "demonstrated antiviral efficacy similar to and at a dose less than one-tenth that of Gilead's Viread® (tenofovir disoproxil fumarate, TDF) 300mg. Data show that because Vemlidy® has greater plasma stability and more efficiently delivers tenofovir to hepatocytes compared to Viread®, it can be given at a lower dose, resulting in less tenofovir in the bloodstream. As a result, Vemlidy® improved renal and bone laboratory safety parameters compared to Viread®."[29] The HBV treatment guidelines provided in "UpToDate," a repository of evidence-based clinical recommendations, supports the use of Vemlidy® over Viread® in most circumstances: "For most patients, we recommend tenofovir alafenamide (25 mg daily) [Vemlidy®] rather than tenofovir disoproxil fumurate (300 mg daily) [Viread®], if available. For those who were originally started on tenofovir disoproxil fumarate, we generally suggest

---

[26] "Phase III Study Evaluating Gilead's Viread for the Treatment of Chronic Hepatitis B Virus Meets Primary Endpoint," *Gilead*, June 6, 2007, available at https://www.gilead.com/news-and-press/press-room/press-releases/2007/6/phase-iii-study-evaluating-gileads-vireadr-for-the-treatment-of-chronic-hepatitis-b-virus-meets-primary-endpoint ("At 48 weeks, 70.8 percent of patients in the Viread® arm (n=250) had a complete response compared to 48.8 percent in the Hepsera arm").

[27] Beasley, Deena, "INTERVIEW-UPDATE 1-HIV franchise, new drugs give Gilead momentum," *Reuters*, August 14, 2008, available at https://www.reuters.com/article/sppage015-n13474477-oishe/interview-update-1-hiv-franchise-new-drugs-give-gilead-momentum-idUKN1347447720080814.

[28] "Teva Announces Exclusive Launch of Generic Viread® in the United States," *Teva*, December 15, 2017, available at https://www.tevapharm.com/news-and-media/latest-news/teva-announces-exclusive-launch-of-generic-viread-in-the-united-states/.

[29] "U.S. Food and Drug Administration Approves Vemlidy® (Tenofovir Alafenamide) for the Treatment of Chronic Hepatitis B Virus Infection," *Gilead*, November 10, 2016, available at https://www.gilead.com/news-and-press/press-room/press-releases/2016/11/us-food-and-drug-administration-approves-gileads-vemlidy-tenofovir-alafenamide-for-the-treatment-of-chronic-hepatitis-b-virus-infection.

switching to tenofovir alafenamide, particularly in older patients and those with risk factors for renal impairment or osteoporosis. Although there is more experience with tenofovir disoproxil fumarate compared with tenofovir alafenamide, tenofovir alafenamide appears to be equally effective and is associated with less renal and bone toxicity."[30]

31. As part of my clinical practice as a generalist focused on inpatient care, I treat patients with newly diagnosed and advanced forms of liver disease, including those secondary to HBV. Although advanced liver disease secondary to HBV is less common in my clinical practice than liver disease secondary to Hepatitis C ("HCV") and alcohol-related liver disease, I have cared for patients newly diagnosed with HBV and patients previously treated for the disease. Based on my clinical experience, both Viread® and more so Vemlidy® offered significant clinical benefits to patients with HBV. As I discuss further in Section VI.A, I understand from the literature that Viread® and Vemlidy® both demonstrate superior outcomes relative to Baraclude (entecavir) for certain patients.[31]

C. Gilead's HBV Opinion Leader Program

32. Gilead's HBV Opinion Leader Program ("OLP") consists primarily of speaker programs and advisory boards, including separate speaking events targeted at HCPs and the

---

[30] Lok, Anna, *supra* note 23.

[31] *See, e.g.,* Park, Ji Won, et al., "Comparison of the long-term efficacy between enetcavir and tenofovir in treatment -naïve chronic hepatitis B patients," *BMC Gastroenterology*, Vol. 17(39), 2017, available at https://bmcgastroenterol.biomedcentral.com/articles/10.1186/s12876-017-0596-7 ("Although either ETV or TDF, overall, may show a comparable long-term antiviral efficacy in treatment-naïve CHB, TDF might be better regimen than ETV in the subgroup of HBeAg-positive CHB, especially with a higher HBV DNA levels."). *See also*, Li, Zhong-Bin, et al., "Switching from entecavir to tenofovir alafenamide for chronic hepatitis B patients with low-level viraemia," *Liver International*, p. 1, January 6, 2021, available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/liv.14786 ("For ETV-treated patients with LLV, switching to TAF is safe enough and superior compared with continuing ETV monotherapy regarding both virological and biochemical benefits.").

community.[32] The OLP is one part of a much broader marketing strategy that also includes advertising, physician detailing, community outreach, and other components. As described in Gilead's annual Brand Plan of Action ("BPOA"), Gilead's OLP focuses on engaging physicians who are able to educate others based on, among other things, their experience with Gilead's products and the diseases they treat. The advisory boards educate Gilead, while speaker programs educate HCPs and the impacted community.[33]

33. I understand that Gilead's OLP advisory boards are organized by its centralized Marketing department, with participation from the Medical Affairs department and oversight from the Business Conduct department.[34] The centralized Marketing department is also responsible for the selection and retention of speakers to Gilead's Speaker Bureau, again with oversight from the Medical Affairs and Business Conduct departments.[35] Sales representatives, overseen by regional directors, select speakers from the Speaker Bureau when organizing

---

[32] Gilead_Purcell_00216621, pp. 55, 59. Note that "product theaters," a specific kind of speaking program, are also considered part of the OLP.

[33] *See, e.g.*, Gilead 2015 Brand Plan of Action, Gilead_Purcell_00216621, pp. 57, 62, 63; *see also* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 55 ("During the annual strategic planning process (e.g., …Brand Plans of Action, …), the Marketing, Commercial Planning, and Medical Affairs departments must submit to Business Conduct a strategic plan for the use of advisors for the coming year."), p. 59 ("Each year during the Brand Plan of Action (BPOA) process, Marketing will develop and submit to Business Conduct a strategic plan for the use of Speakers for the coming year.").

[34] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 55 ("During the annual strategic planning process… the Marketing and Medical Affairs departments must submit to Business Conduct a strategic plan for the use of advisors for the coming year."). *See also*, Rough Transcript from 30b6 Deposition of Erica Chien, April 30, 2021, pp. 119:19-121:4 ("ad boards can be conducted by different departments, but for marketing, say, it would be the marketing department that would then be responsible for determining when there is a need to ad board and what kind of advice they are looking for and then based on there may be, you know, different sources to, you know, figure out what advisors might have that expertise to be appropriate."). I reserve the right to amend or supplement this report in the event that the official transcript from the 30b6 deposition of Erica Chien differs from the rough transcript.

[35] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 66 ("The Marketing Department is responsible for the selection and retention of Professional and Community Speakers, subject to review and approval by Sales, Medical Affairs, and Business Conduct.").

speaker programs in primarily four geographic regions: Northeast, Atlantic, Midwest, and West.[36]

34. At a high level, Gilead leverages its advisory boards to gain information directly from physicians on the HBV patient population, as well as their experiences treating patients with Gilead products. For example, in advisory boards shortly after Vemlidy®'s launch, advisors informed Gilead that they needed to "produce and disseminate multilingual [Vemlidy®] patient educational resources through various media/channels in communities most impacted by CHB."[37] As I discuss further in Section IV.B.2, Gilead documents indicate that it relies on this kind of information to inform clinical trials and patient outreach to ensure their treatments are tested on and accessible to those who most need them.

35. Conversely, Gilead's speaker programs focused on educating HCPs and the community on its products and HBV more generally. Gilead's Business Conduct Manual indicates that "[t]hrough its speaker bureaus for professional… and community based audiences…, Gilead retains qualified third-party healthcare professionals (HCPs), peer educators, case managers, and patients to speak on Gilead's behalf concerning its products and the diseases that they treat consistent with their on-label uses."[38] Specifically, "[s]peakers for product-related Professional Programs educate healthcare professionals (HCPs) about Gilead products and the diseases treated by those products consistent with their on-label use… Speakers for non-product Professional or Community Programs educate their audiences about the diseases

---

[36] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 71 ("Therapeutic Specialists (TSs) [among others], schedule, organize, and implement Professional [Speaker] Programs with oversight from their Regional Directors.").

[37] Gilead_Purcell_00188235, p. 96.

[38] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 63.

encompassed by Gilead's therapeutic areas, including but not limited to disease state and progression, screening, barriers to care, and/or epidemiology information."[39]

36. Gilead's efforts to engage with the HBV community go beyond its OLP. For example, in 2016 Gilead launched "BE ABOUT IT," a 40 minute, unbranded, documentary film about living with and receiving treatment for HBV. The programming around the film included a premier at CAAM Asian American Film Festival, as well as three local market screenings in New York, Los Angeles, and Honolulu. As a follow up to the launch, Gilead provided community screening kits that included "materials and step-by-step instructions to enable organizations to host local screenings of their own" to "relevant groups through outreach to Asian American student organizations, community groups, churches, medical schools, liver health and hepatology centers and advocacy organizations."[40]

37. Exhibit 2 shows the mix of Gilead OLP events over the at-issue time period. Community events [redacted] speaker events during the at-issue period, [redacted] non-HCP attendees seeking education on HBV (see Exhibit 11).[41]

[39] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 71.

[40] *See, e.g.,* Gilead_Purcell_00188235, pp. 38 - 39.

[41] Speaker Program Spend Reports.

Excerpt of Exhibit 2[42]

38. Exhibit 3 below shows the mix of Gilead speaker events over the at-issue time period by product. Notably, [redacted] Gilead speaker events focused on general HBV education rather than Gilead products. These events are labeled as "unbranded" events in Gilead's data, indicating that the events were not branded by Gilead and instead were focused on the HBV disease state rather than Gilead's products.[43]

42 

43 *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 26 ("Unbranded. Materials that do not mention a product or include brand colors and logos and are intended to educate HCPs, patients, or the general community on particular disease states are considered unbranded and are subject to different standards and rules of compliance.").

Excerpt of Exhibit 3[44]

39. As discussed in Section III.A, HBV is a unique disease, with substantial challenges related to under-screening, under-reporting, and under-treatment, despite major health consequences and corresponding costs if left untreated. Studies have shown a "significant beneficial effect of educational interventions on patient disease knowledge, patient behavioral modifications including testing for the disease and uptake of vaccination, willingness to commence and adhere to treatment, and other outcomes such as self-efficacy and vitality/energy scores,"[45] confirming the importance of the education provided to patients (and caregivers) through Gilead's community events.

IV. GILEAD'S HBV MARKETING PROGRAMS SERVED LEGITIMATE PURPOSES AND WERE CONSISTENT WITH INDUSTRY PRACTICE

40. Pharmaceutical manufacturers frequently engage in different forms of marketing to patients and HCPs. Marketing efforts include direct-to-consumer advertising, community

[44] Limited to completed AHM speaker events and all non-AHM speaker programs. See note 42 for advisory board identification methodology. Speaker Program Spend Reports; Advisory Board Spend Reports.

[45] Shah, Hemant, et al., *supra* note 13.

education programs, detailing to individual physicians, and peer-to-peer HCP speaker programs, among others. One important objective of pharmaceutical marketing is to ensure that physicians, patients, and caregivers have information on the disease state, diagnosis, and new treatments, as well as updated information on existing treatments, all of which can improve patient access to and quality of treatment. Marketing efforts directed at physicians can be particularly useful for less experienced physicians who want to leverage the experience of others, and physicians who maintain busy schedules treating patients and want to ensure their knowledge of treatment options is up to date.[46]

41. Each form of marketing offers a different point of contact between the manufacturer and physicians, patients, or caregivers, but all provide a potential opportunity to educate on the benefits of a particular product for a specific disease state and patient population. Prescribers expand their knowledge of products and treatment approaches through a number of sources, including these marketing efforts, as well as clinical guidelines, scientific publications, outcomes research, clinical trial results, drug labeling, continuing medical education, and peer networks. The multiple sources of information can be particularly valuable for physicians who prescribe limited amounts of a given drug and cannot rely on the cumulative experience that stems from prescribing a drug to many patients.

42. Physicians are required to review, assess, and interpret the myriad sources of medical, scientific, and corporate information as part of their regular practice. While each piece

[46] Savage, Christine, "Ending Physician Speaker Programs May Not Be A Good Thing," Law 360, March 11, 2014, available at https://www.choate.com/images/content/1/1/v2/1107/Savage-Ending-Physician-Speaker-Programs-May-Not-Be-A-Good-Thing.pdf ("[I]t remains unrealistic to expect clinicians to carve out sufficient time to sort through and keep up with the latest research while maintaining full patient panels and satisfying other obligations. It is also unrealistic to expect that academic detailing […] or government sponsored evidence-based medicine programs will be able to conduct the same level of outreach as industry-backed promotional programs.").

of information may take a different form, physicians are trained to compile and synthesize that information in making prescribing decisions. Physicians do not merely follow recommendations from a single source of information; rather, they often require confirming evidence before altering their prescribing behavior.[47] For example, physicians are aware that promotional events and materials may spotlight a specific drug, but use their training and knowledge to accurately interpret the information, consider and relate that information to other sources, and ultimately make the best treatment decisions for their patients.[48]

43. In my experience as a physician, pharmaceutical marketing can be an important mechanism for physicians to receive the information necessary to make treatment decisions. I am far from alone in that view. According to a Kaiser Family Foundation survey, 74 percent of physicians report that information received from pharmaceutical representatives is useful, with

---

[47] Rodolfo, Aldir E., et al., "Practicing and resident physician's view on pharmaceutical companies," *Journal of Continuing Education in the Health Professions,* Vol. 16, 1996, pp. 25-32, at p. 25, available at https://journals.lww.com/jcehp/Abstract/1996/16010/Practicing_and_resident_physicians__views_on.3.aspx. *See also* Fischer, Melissa, et al., "Prescribers and pharmaceutical representatives: why are we still meeting?" *Journal of General Internal Medicine*, Vol. 24(7), May 8, 2009, pp. 795 - 801, at p. 795, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2695530/.

[48] Weber, Michael A. et al, "Association of Clinical Researchers and Educators a Statement on Relationships Between Physicians and Industry," *Endocrine Practice,* November/December 2012, Vol. 8 No. 6, pp. 1029-1037, at p. 1033.

81 percent noting that the information is accurate.[49] Access to pharmaceutical sales representatives can also provide physicians with important information on adverse effects.[50]

44. Speaker and advisory board programs are common components of pharmaceutical marketing strategies, and it is widely recognized that both can provide benefits to physicians and patients. For example, speaker programs can help disseminate information to improve patient treatment. Advisory boards can provide critical feedback to pharmaceutical companies about patient treatment, drug side effects, insurance coverage, and other data points, that pharmaceutical companies then incorporate into their marketing strategies to improve messaging and ultimately treatment outcomes.

45. That said, speaker and advisory board programs are still only one component of Gilead's overall marketing approach, which is designed to educate and inform physicians of the benefits of their products relative to others, and provide clinical information on their use. For example, Gilead documents show that marketing strategies for Viread® and Vemlidy® included geo-targeted advertising, electronic medical records advertising, banner and journal advertisements, sales force calls, convention booths, partnerships with medical associations, development of mini-documentaries, and hepatitis B segments on radio/TV programs, in addition

---

[49] 15 percent of physicians find information from drug representatives "very useful" and 59 percent say the information is "somewhat useful." 9 percent of physicians say the information is "very accurate" and 72 percent say it is "somewhat accurate." "National Survey of Physicians Part II: Doctors and Prescription Drugs," *The Kaiser Family Foundation*, March 2002, p. 5, available at https://tinyurl.com/h294d6ax. *See also*, "Pharmaceutical Marketing in Perspective: It's Value and Role as One of Many Factors Informing Prescribing," *PhRMA*, available at https://tinyurl.com/kw295zec (more than 90 percent of physicians said that interactions with manufacturers helped them learn about potential side effects, new indications, and benefits and risks of treatment).

[50] For example, physicians in practices with low access to pharmaceutical sales representatives were slower to respond to updated information on adverse effects such as black box warnings than physicians with greater access. *See* Chressanthis, George A., et al., "Can access limits on sales representatives to physicians affect clinical prescription decisions? A study of recent events with diabetes and lipid drugs," *Journal of Clinical Hypertension*, Vol. 14(7), July 2012, pp. 435 - 446, at p. 435, available at https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1751-7176.2012.00651.x.

to speaker programs.[51] [redacted][52]

46. In this section, I identify the characteristics that tend to be associated with legitimate speaker programs and advisory boards. Additionally, I provide evidence that the design of the speaker and advisory board programs implemented by Gilead for HBV was consistent with the characteristics of legitimate programs. In Section V, I identify characteristics that have been identified as raising concerns around improper physician payments, and conclude that the speaker and advisory board programs implemented by Gilead for HBV were inconsistent with the characteristics of improper programs.

A. Gilead's HBV physician speaker programs served legitimate purposes and were consistent with industry practice

1. *Physician speaker programs are a common industry tool for achieving legitimate and socially beneficial purposes*

47. Physician speaker programs are one type of marketing tool that a pharmaceutical company may use to promote its drugs. Speaker programs may focus on new drugs, existing drugs, or a disease state more generally. For drugs that are new to market, the programs offer a source of information about a treatment option that many physicians may have little experience prescribing for their patients. For older drugs, the programs may offer new information as treatment options change and evolve over time (e.g., as a result of new clinical testing), or with the entry of other products. This can include information on new indications and new populations, as well as updated information on side effects and efficacy based on post-marketing

[51] Gilead_Purcell_00216621, pp. 41, 45, 46, 50, 81; and Gilead_Purcell_00188235, pp. 38-41, 71.

[52] I calculated the share of estimated marketing costs as the sum of estimated costs for "Speaker training" and "Speaker Website & MGMT" divided by the sum of all other estimated costs for strategic objectives. Costs for strategic objectives do not include Advisory Boards or costs for programs outside of marketing. *See* Gilead_Purcell_00216621, p. 91.

and real-world studies. For disease states, the programs offer information on disease progression, screening, diagnosis rates, prevalence in specific communities, and drug resistance. This information can be especially valuable for diseases such as HBV, which disproportionately impacts certain populations and may often be treated by primary care physicians with less HBV experience.

48. Furthermore, messaging from experts in a particular disease state can be useful to a physician population that is expanding due to increased treatment of the disease in less specialized settings (for example, primary care settings). Speaker program messaging may reach many physicians who have less experience treating the relevant patient population and new patients who are unfamiliar with available treatments. For these physicians, speaker programs present an opportunity to interact with and ask questions of physicians who have significant experience treating patients with a specific condition, which they may be less likely to get through their own experience or local professional networks of physicians in the same specialty.

49. Industry-sponsored educational events are well-regarded by many healthcare providers. For example, one survey showed that 93 percent of health care practitioners value industry-provided information on new drugs, and over 80 percent value industry sponsored physician speaker programs and continuing medical education. Of the survey participants who had attended industry-sponsored education programs, the majority said they gained knowledge or skills that were helpful in their practice.[53] Gilead's own market research indicated that speaker programs are HCPs' preferred method of receiving HBV information and product education.[54]

---

[53] Sullivan, Thomas, "Survey Shows Physicians Have High Regards for Industry Interactions," *Policy & Medicine,* May 5, 2018, available at https://www.policymed.com/2011/04/survey-shows-physicians-have-high-regards-for-industry-interactions.html.

[54] Gilead_Purcell_00207927, p. 2.

Individual physicians have reiterated the benefits of speaker programs, with one doctor noting that events provide "up-to-date information on [diseases] from world-known authorities," and that 90 percent of his lectures at speaking events are about a disease or medical condition with only 10 percent discussing a specific drug.[55]

50. Disseminating information on how to better identify and treat the relevant patient population may lead to expanded use of the manufacturer's drugs. As such, the potential overall benefits of these programs to all parties involved make them a key component of pharmaceutical manufacturers' marketing efforts. Many pharmaceutical companies have made use of promotional speaker programs, with one survey from 2013 finding that approximately 80 percent of surveyed pharmaceutical companies had speaker programs in place.[56] Part of the benefit of physician speaker programs compared to marketing by non-physician sales representatives is that physician speaker programs allow pharmaceutical companies to engage physician educators. These physician educators can be effective at conveying information and affecting the practice patterns of their peers. For example, a review of randomized studies found that physician educators (referred to as "key opinion leaders", or "KOLs") are likely to disseminate information that improves compliance with evidence-based practice.[57] Pharmaceutical companies have worked for many years with physician educators to disseminate information on research and

---

[55] Nugent, Karen, "Dollars for Docs lucrative," *The Telegram*, May 15, 2011, available at https://www.telegram.com/article/20110515/NEWS/105159768/-1/NEWS07.

[56] "Nearly Half of Pharma's Promotional Speaker Programs Teams have Been in Place Less than Three Years," *businesswire*, March 14, 2013, available at https://tinyurl.com/3yyxswav.

[57] Flodgren, Gerd, et al., "Local opinion leaders: effects on professional practice and healthcare outcomes," *Cochrane Database of Systematic Reviews,* 2019, available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000125.pub5/full.

development throughout the medical community.[58] Furthermore, because of their experience treating patients, these physician educators are better able to candidly respond to questions raised by audience members than non-HCP sales representatives. Speaker programs also have the benefit of potentially being more cost effective when compared to detailing of individual physicians because speaker programs allow a single speaker to present information to multiple HCPs at a time.[59]

51. While speaker programs are just one component of pharmaceutical manufacturer marketing strategy, they play an important role in providing valuable information to HCPs and the community through those who have the most experience in treating a specific disease. My review of Gilead's documents leads me to believe that its speaker programs had these intended effects.

2. *Gilead's physician speaker programs for Viread® and Vemlidy® served legitimate purposes*

52. My review of Gilead documents indicates that the purpose and design of the Viread® and Vemlidy® physician speaker programs at issue in this case are to educate HCPs and the community on HBV generally and on Gilead products available to help treat that disease.[60]

---

[58] "Looking out for a hero! An Insider's Insight into Key Opinion Leader Identification and Profiling," *Niche Science & Technology*, 2020, available at http://www niche.org.uk/asset/insider-insight/Insider-KOLIP-P.pdf.

[59] Eisenmann, Marianne, et al., "Measuring the Effectiveness of Speakers Programs," *Institute for Public Relations*, February 2007, p. 5.

[60] This is consistent with Gilead employee testimony. For example, Ivan Tai, a current Senior TS, HBV Sales Northeast, testified that the purpose of a speaker program "is to education and also promote [Gilead's] product based on the science." Graham Warden, a current Executive TS, HBV Atlantic, testified that the speaker events always provided "content that is relevant to the disease state and to the knowledge for these physicians and healthcare providers in general to have." *See* Transcript from Deposition of Ivan Tai, October 5, 2020, p. 32:14-20; and Transcript from Deposition of Graham Warden, September 23, 2020, p. 297:2-10.

53. As noted in Section III.C, Gilead's Business Conduct Manual indicates that speakers for Gilead product-related Professional Programs should "educate healthcare professionals (HCPs) about Gilead products and the diseases treated by those products consistent with their on-label use."[61]

54. Gilead documents associated with the physician speaker programs confirm that these rules were carried out in practice. Physician speaker program presentations for Viread® and Vemlidy® provide FDA-approved information, such as safety and efficacy study results. Due to the promotional nature of some of these events, speakers are instructed to discuss only FDA-approved information and to not discuss topics such as off-label prescribing.[62] Discussion questions, particularly during the "roundtable" version of Vemlidy® and Viread® speaker programs, are designed to gauge participants' understanding of the information presented, such as the black box warning, the renal warning, or subjects who are enrolled in drug studies.[63]

55. The educational purpose and design of Gilead's HBV speaker programs is further apparent from the fact that [redacted] of those events were focused on general HBV education rather than on Gilead products (see Section III.C and Exhibit 3). Gilead's Business Conduct Manual indicates that "non-product" professional and community programs educate their audiences about the "disease state and progression, screening, barriers to care, and/or epidemiology information."[64] Gilead's Executive Director of HBV Sales & Marketing, Marc Aquino, testified that "the objective of community programs is to… help the community and

---

61 *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 71.

62 Gilead_Purcell_00006323; Weber, Michael A. et al, *supra* note 48, at p. 1033.

63 Gilead_Purcell_00006323.

64 *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 71.

raise awareness for these diseases which are… underdiagnosed and undertreated."[65] These are precisely the issues that are a unique challenge to properly treating HBV, where patients suffer from under-screening, under-reporting, and under-treatment. Furthermore, a former Gilead employee testified that these community programs were aimed at addressing the challenges, misinformation, and stigma patients faced surrounding HBV, including transmission facts and association between HBV and liver cancer.[66]

56. Gilead's HBV speaker programs also help to disseminate information about HBV treatments. From my perspective as a physician, knowledge of risks associated with HBV treatment is concentrated among a relatively small number of physicians who treat a disproportionate share of HBV patients, and consequently write a disproportionate share of HBV drug prescriptions. For example, as described in Section V.C, a large share of HBV drug prescribing is concentrated within a small set of physicians while many other physicians are more infrequent prescribers. These physicians have the most relevant experience, and thus are the best positioned to educate less-informed or less-experienced physicians and non-prescribing HCPs. Gilead's HBV speaker programs facilitate that information transfer: Experienced physicians with more information can share that information in a direct presentation or through the Q&A portion of an event. This provides significant benefits for the attendees, who are able to receive information directly from their more experienced speaker-colleagues, rather than from relatively less experienced (and non-medically-trained) pharmaceutical sales representatives. Additionally, by drawing on a consistent group of highly specialized and knowledgeable

[65] Transcript from Deposition of Marc Aquino, August 25, 2020, pp. 10:20-22, 54:3-10.

[66] Transcript from Deposition of Ilija Zlatar, November 11, 2020, pp. 10:8-12, 39:9-41:3.

physicians to speak at these programs, Gilead promotes uniformity and consistency in its educational messaging.

57. The geographic distribution of Gilead HBV events also indicates an educational purpose and design. By holding localized speaker programs in areas where key speakers and many relevant attendees are already concentrated, Gilead is able to supply information on HBV and its treatments where it is most needed. This can also mean that speaker programs can produce efficiency gains in disseminating knowledge relative to, for example, broad detailing across the nationwide prescriber population.

58. Documents from Viread® and Vemlidy® professional speaker programs provide strong evidence of the educational benefits provided to HCP attendees. The presentations frequently begin with general HBV information that is not specific to Gilead products, which is often sourced from peer reviewed studies. Examples include information on the cellular mechanism of fibrogenesis, fibrosis progression in CHB, risk of cirrhosis by fibrosis stage, cirrhosis risk factors, and the relationship between HBV DNA level and risk of cirrhosis.[67] In addition, the presentations provide FDA-approved information specific to Viread® or Vemlidy®. This can include recommendations for dosing and dosing adjustments, discussion of patients for which treatment is not recommended, overview of mechanism of action based on clinical trials and peer reviewed studies, warnings/precautions and instructions on when to test or suspend treatment, information on adverse effects and drug interactions, and use in specific populations (including disclosure of when there is no data on specific populations).[68] The

---

[67] Gilead_Purcell_00006433, pp. 5 - 11.

[68] Gilead_Purcell_00006213, pp. 6 - 10, 12 - 14, 27, 30, 32 - 40; Gilead_Purcell_00006433 at pp. 4, 13 - 15, 27, 28, 40 - 41, 43.

presentations include detailed overviews of clinical trials, such as information on study design, baseline characteristics and treatment history, primary endpoints, subgroup analyses, alanine aminotransferase ("ALT") normalization, serology results, and resistance rates.[69] This information, especially when presented by a physician with first-hand experience treating HBV patients, can provide significant educational benefits to HCPs.

59. Relators allege that these speaker events were predominately social.[70] I have seen no evidence to support such an allegation. Moreover, that allegation is inconsistent with testimony from Gilead speakers. For example, Dr. Calvin Pan testified that he believed that Gilead speaker programs provided educational value to attendees and that he had never attended a hepatitis B speaker program that was "purely social [in] nature without any medical discussion" or that was held at a venue that was not conducive to an educational exchange.[71] Dr. Pan testified that he had received email feedback from attendees telling him "how wonderful the program they [] attended was and what they learn[ed] from the program" as well as asking him "follow up questions [on] patients management care."[72] Dr. Pan further testified that he believed Gilead's HBV speaker programs improved patient care outcomes and health care quality, as well as helped to address disparities in the Asian community.[73]

60. Documents associated with Gilead's community speaker programs point to similar educational benefits, with clear efforts to tailor programming to at-risk communities. For

---

69 Gilead_Purcell_00006213 at pp. 16-25; Gilead_Purcell_00006433 at pp. 18-24.

70 Complaint, ¶ 148.

71 Rough Transcript from Deposition of Calvin Pan, April 22, 2021, pp. 232:23-233:3, 233:21-234:6. I reserve the right to amend or supplement this report in the event that the official transcript from the deposition of Calvin Pan differs from the rough transcript.

72 Rough Transcript from Deposition of Calvin Pan, April 22, 2021, pp. 234:2-15.

73 Rough Transcript from Deposition of Calvin Pan, April 22, 2021, pp. 234:16-235:4.

example, in 2013 Gilead collaborated with a Hepatitis Community Specialist in Santa Clara, CA to host a high-profile "Hep B Free" event that included free HBV screening as well as four community speaker programs in three different languages, targeting the Asian Indian, Vietnamese, and Chinese communities.[74] In late 2013, a Gilead sales representative in the Midwest region collaborated with Dr. Ping Wang to "create a program with English slides and translation into Arabic," to "provide a safe environment - that is culturally sensitive - to educate and screen parents [in the Arabic community]." The effort resulted in an event with 106 attendees, 67 of whom were screened.[75] Similarly, Leilani Larson, Gilead's Senior Director of HBV Marketing, testified that community programs typically included regional speakers who were able to speak to audience members in their native tongue.[76] At an event that Relator Groome helped plan, Gilead hosted a "newly diagnosed Hepatitis Education Workshop," targeted at patients who had tested positive at a free hepatitis B & C screening clinic the prior month, at which 404 individuals had been screened, with 40 positive for HBV, 37 for HCV, and 3 coinfected.[77] Educational materials presented at community events like these include a substantial amount of information, such as how HBV is transmitted, risk factors for infection, symptoms, disease progression, common false and stigmatizing information, testing, interpreting test results, what treatment entails (i.e., not specific to Gilead products), access to treatment, preventing future transmission, etc.[78]

---

74 Gilead_Purcell_00165845.

75 Gilead_Purcell_00045029.

76 Transcript from Deposition of Leilani Larson, September 4, 2020, pp. 33:17-34:13.

77 Gilead_Purcell_00279891.

78 Gilead_Purcell_00142135.

61. As I noted earlier in this report, there are major detrimental health consequences associated with HBV if left untreated, yet despite these costs many HBV patients are undiagnosed and do not receive appropriate care. Well-designed professional and community speaker programs can be an effective way of expanding treatment and benefiting patients. This expanded treatment by itself is not an indicator of improper prescribing; there is and should be a strong public desire, and large benefit, to finding and addressing the untreated population. I find that Gilead's HBV speaker programs were designed with the intention of achieving these patient benefits.

B. Gilead's HBV advisory board programs served legitimate purposes and were consistent with industry practice

1. *Advisory board programs are a common industry tool for achieving legitimate and socially beneficial purposes*

62. Pharmaceutical companies make use of advisory boards to solicit professional advice and insights relevant to their products.[79] Advisory boards are common across a variety of business sectors and consist of experts who have substantial experience in their respective industries.[80] Advisory boards provide valuable strategic advice and support to organizations. These groups offer managers and business owners an outside and independent perspective and give credibility in the market with proven experts supporting a company or its products.[81]

63. In the pharmaceutical industry, advisory boards help companies understand the physician perspective on specific therapeutic areas, the external environment, clinical strategies,

---

[79] Powrie-Smith, Andy, "Working Together for Patients: Advisory Boards*," European Federation of Pharmaceutical Industries and Associations*, February 12, 2015, available at https://www.efpia.eu/news-events/the-efpia-view/blog-articles/151202-working-together-for-patients-advisory-boards/.

[80] Alkurd, Ibrahim, "The Benefits Of An Advisory Board For Success," Forbes, September 3, 2020, available at https://www forbes.com/sites/theyec/2020/09/03/the-benefits-of-an-advisory-board-for-success/?sh=441c8ff17557.

[81] Alkurd, Ibrahim, *supra* note 80.

and unmet medical need. The knowledge pharmaceutical companies gain from advisory boards can help provide beneficial information, education, and training surrounding their products, leading to better patient treatment.[82] Furthermore, advisory boards can provide HCPs the opportunity to help design clinical trials or voice concerns they have over clinical trial and/or real-world safety or efficacy. This in turn allows pharmaceutical companies to address issues that they may not have otherwise identified.[83] Advisory boards also "promote positive relationships with the scientific community [and] can be considered a critical activity for the success of a pharmaceutical company and its products."[84] The use of advisory boards is common in the pharmaceutical industry. Surveys of biopharmaceutical and medical device companies have found that nearly 60 percent of companies maintain physician and clinical advisory boards, with many companies conducting more than 100 advisory board meetings per year across different geographic and/or therapeutic areas.[85]

64. Based on my review of Gilead's documents, I find that Gilead's advisory board programs were well designed and frequently incorporated feedback from trusted advisors into future education and research efforts.

---

82 Powrie-Smith, Andy, *supra* note 79.

83 Baria, Katherine et al., "Advisory Boards: Words of Advice and a 10-point Checklist," *The MAP Newsletter,* Mar 10, 2020, available at https://ismpp-newsletter.com/2020/03/10/advisory-boards-words-of-advice-and-a-10-point-checklist/; Dyer, Samuel, et al., "Nine Key Elements To Ensure Advisory Board Success," *PM 360*, Jun 17, 2014, available at https://www.pm360online.com/nine-key-elements-to-ensure-advisory-board-success/.

84 Baria, Katherine et al., *supra* note 83.

85 "Benchmarking Advisory Board Management At Large Pharmaceutical & Medical Device Organizations," *Best Practices LLC*, p. 6, available at https://www.best-in-class.com/bestp/domrep.nsf/products/benchmarking-advisory-board-management-at-large-pharmaceutical-medical-device-organizations; "Best Practices in Managing Board Meetings in the Global Market," *Best Practices LLC*, at pp. 5-6, available at https://www.best-in-class.com/bestp/domrep.nsf/products/best-practices-managing-board-meetings-global-market; and "Current Practices in Pharmaceutical Advisory Board management are Highlighted in New Report," *Cision PR Newswire*, February 17, 2017, available at https://www.prnewswire.com/news-releases/current-practices-in-pharmaceutical-advisory-board-management-are-highlighted-in-new-report-300409643.html.

2. *Gilead's advisory boards for Viread® and Vemlidy® served legitimate purposes*

65. My review of Gilead documents leads me to conclude that Gilead advisory boards are designed to educate Gilead on physician real-world experience treating HBV, which ultimately results in lower barriers to diagnosis and treatment, and safer and more effective medications, for patients.[86] As with physician speaker programs, the concentrated nature of HBV prescribing makes advisory boards an efficient way for pharmaceutical companies generally, and Gilead specifically, to collect feedback from HCPs who can provide information based on substantial day-to-day experience treating HBV patients. Advisory boards provide an opportunity for Gilead to better understand real-world safety and efficacy concerns related to Viread® and Vemlidy®, barriers to HBV diagnosis and treatment (for example, access to testing, stigma, and cost), and patient perceptions.

66. Gilead documents provide insight into the information that was collected during Viread® and Vemlidy® advisory board meetings. "Executive Summary" slide decks consolidate the information obtained from HCPs during advisory board meetings and provide an overview of how Gilead can use the information to improve its products. For example, in one advisory board meeting, HCPs reported a desire to see additional types of data, such as data on safety beyond 48 weeks, lipid issues with TAF, and on specific populations (e.g., those who are pregnant or breastfeeding).[87] Gilead used this feedback to make specific recommendations for future clinical trials.[88]

---

[86] Gilead_Purcell_00216621, at pp. 57, 62, 63.

[87] Gilead_Purcell_00174611, p. 14.

[88] Gilead_Purcell_00174611, p. 15.

67. Executive summaries show that robust clinical discussions took place during Gilead's Viread® and Vemlidy® advisory board programs. HCPs have described the advisory boards as providing a "healthy discussion."[89] For example, advisory boards have resulted in discussions of data on regression of liver fibrosis and the need for long-term treatment for HBV, necessity of resistance testing, and HCP perceptions of long-term safety data.[90] Additionally, such discussions have provided Gilead with insight into barriers to treatment such as differences in CHB awareness among different patient populations, HCP adherence to CHB screening guidelines, and patient characteristics that influence CHB treatment selection.[91]

68. Relatedly, Gilead's advisory boards for Viread® and Vemlidy® are geared toward providing Gilead with valuable information on HBV treatment from an HCP perspective. For example, Viread® advisory board meetings allowed Gilead to gain an understanding of how HCPs identify and manage lamivudine resistance in their practices.[92] This information is valuable to Gilead – and ultimately to patients – as lamivudine-resistant patients are a group of already diagnosed HBV patients that may benefit from switching to Viread®. Additionally, advisory board meetings allowed Gilead to obtain information from HCPs regarding the ways in which comorbidities and age can impact CHB treatment selection as well as information on barriers to treatment, such as CHB screening and issues managing prior authorization.[93] Gilead used this information to combat barriers that prevent patients from being diagnosed and ultimately initiating treatment with Viread® or Vemlidy®. The meetings also provided an

---

89 Gilead_Purcell_00006709, p. 22.

90 Gilead_Purcell_00006709, pp. 9, 19.

91 Gilead_Purcell_00006709, pp. 7, 8, 10.

92 Gilead_Purcell_00007027, p. 3.

93 Gilead_Purcell_00007027, pp. 3, 21; and Gilead_Purcell_00006741, pp. 7, 11.

opportunity for Gilead to understand HCPs' reactions to Viread® and Vemlidy® clinical trial data and understand whether the results were consistent with what HCPs observed in their clinical practice.[94] Collectively, this information allowed Gilead to gain insight into the real-world data observed by HCPs in their clinical practices. It also provided Gilead with useful information that could be used to adapt their marketing strategies to present information that HCPs were most interested in learning about. For example, recommendations based on Vemlidy® advisory boards included targeting speaker programs specifically for NPs and PAs, as these are often the first-line contacts for CHB patients, as well as highlighting differences in ALT normalization compared to Viread®.[95]

69. Given the underserved and underdiagnosed HBV population, Viread® and Vemlidy® advisory boards also provide Gilead with an opportunity to understand the types of barriers to diagnosis and treatment that HBV patients face. For example, in one advisory board meeting an HCP reported that primary care physicians are reluctant to screen for HBV and thus recommended educating them. Other HCPs discussed how stigma in communities at risk of HBV is a common cause for not testing and/or treating patients.[96]

V. GILEAD HBV SPEAKER AND ADVISORY BOARD PROGRAMS DID NOT DEMONSTRATE CHARACTERISTICS ASSOCIATED WITH IMPROPER INFLUENCE ON PHYSICIAN PRESCRIBING

70. While the government recognizes that speaker and advisory board programs have the potential to provide significant benefits to physicians and other HCPs, caregivers, pharmaceutical companies, and ultimately patients, it also provides guidance on how to ensure payments associated with such programs do not lead to improper influence on physician

[94] Gilead_Purcell_00007207, p. 37; and Gilead_Purcell_00006741, pp. 7, 15.

[95] Gilead_Purcell_00006741, pp. 12, 17.

[96] Gilead_Purcell_00006709, pp. 7, 14.

prescribing. In 2003, the OIG published compliance guidelines for pharmaceutical companies and their relationships with physicians, including appropriate conduct for speaker and advisory arrangements, to ensure programs comply with the federal False Claims Act ("FCA") and Anti-Kickback Statute ("AKS").[97] The OIG notes that while these relationships may pose a risk for potential fraud, "fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern."[98] Further, they recognize that arrangements with physicians should be "reviewed in light of the totality of all facts and circumstances bearing in mind the following factors, among others:" the degree of influence the physician has on generating business for the manufacturer; whether or not volume or value of business is directly or indirectly taken into consideration in determining remuneration; if the compensation is of fair market value and reasonable for the services rendered by the physician; if the remuneration has the potential to impact federal health care program costs and leads to inappropriate utilization; if acceptance of payment would diminish objectivity of the physician.[99] These guidelines also specify that speaker service agreements

---

97 In 2020, the OIG released a new set of guidelines specifically for speaker programs. These guidelines were not in effect during the relevant time period at issue. While the statement adjusts prior guidance surrounding speaker programs in general and further describes the potential for improper inducement of HCPs to write prescriptions for the company's products, it clarifies the need for individual assessment to evaluate the validity of specific speaker programs. The statement overall reinforces the idea that these programs can be beneficial as long as they follow certain guidelines. Specifically, the new statement explains that "the lawfulness of any remunerative arrangement, including speaker program arrangements, under the anti-kickback statute depends on the facts and circumstances and intent of the parties," indicating that appropriate speaker programs that follow the expressed guidelines can exist without being liable under the FCA and AKS. See "Special Fraud Alert: Speaker Programs," Department of Health and Human Services: Office of Inspector General, November 16, 2020, p. 5, available at https://oig hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.

98 Duke, Elizabeth, "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," Department of Health and Human Services: Office of Inspector General, Federal Register, Vol. 68, No. 86, May 5, 2003, 23731-23743, at 23738.

99 Duke, Elizabeth, *supra* note 98, at p. 23737.

should be set out in writing with all facts documented prior to payment and that there should be a legitimate need for the service.[100]

71. The 2003 OIG guidance is aligned with The Pharmaceutical Research and Manufacturers of America's ("PhRMA") 2002 "Code on Interactions with Healthcare Professionals" industry supported guidelines.[101] PhRMA represents over 30 leading biopharmaceutical research companies to promote public policy that supports medical research to address patient needs.[102] Indeed, the OIG has described the PhRMA Code as "provid[ing] useful and practical advice" and that a company's compliance with the PhRMA Code "will substantially reduce the risk of fraud and abuse and help demonstrate a good faith effort to comply with the applicable federal health care program requirements."[103] In 2009, PhRMA built on the OIG guidelines to publish a new code on pharmaceutical interactions with HCPs. [104] In this section, I determine whether Gilead's policies and practices align with the OIG and PhRMA guidelines.

72. Given the strong overlap in OIG and PhRMA guidelines for speaker programs and advisory boards, in this section I discuss both speaker and advisory board events collectively, and identify distinctions where appropriate. I begin by reviewing the OIG and PhRMA guidelines alongside Gilead's own guidelines, and then examine whether the evidence

---

100 Duke, Elizabeth, *supra* note 98, at p. 23738.

101 Duke, Elizabeth, *supra* note 98, at p. 23737.

102 "About," *PhRMA*, available at https://phrma.org/About; "Members," *PhRMA*, available at https://www.phrma.org/About/Members.

103 Duke, Elizabeth, *supra* note 98, at p. 23737.

104 "Code on Interactions with Healthcare Professionals," *PhRMA*, July 2008, pp. 3, 7-10, available at https://tinyurl.com/zu4cfurw ("PhRMA Guidelines").

on Gilead's speaker and advisory board events is consistent with adherence to these guidelines, indicating they were unlikely to result in improper influence.

73. Additionally, Relators' allegations focus on "issues" with speaker and advisory board programs that were not addressed in the 2003 OIG guidelines or 2009 PhRMA guidelines, such as "inappropriate" attendees (e.g., office staff),[105] and events that were "predominately social" (I addressed this in Section IV.A.2)[106] As explained below, I believe these complaints ignore important aspects of the practice of medicine, especially for a socially stigmatized disease such as HBV.

A. Gilead's internal guidelines were closely aligned with the OIG and PhRMA guidelines on speaker and advisory board programs

74. As a first step to determine whether Gilead's speaker and advisory board programs demonstrate characteristics associated with improper influence, I reviewed Gilead's Business Conduct Manual to see how well Gilead's internal rules aligned with OIG and PhRMA guidance. Gilead's rules in its Business Conduct Manual address the key OIG and PhRMA criteria (which are in italics):

a. *Selection of speakers should be determined based on defined criteria such as medical expertise and reputation or knowledge and experience with a particular therapeutic area.* [107] Gilead requires that professional speakers must have "[c]linical expertise in the relevant therapeutic area… Additional criteria can include experience with the use of relevant Gilead products; authorship of academic or other relevant articles in peer-reviewed journals…," etc. Further,

---

105 Complaint, ¶¶ 150 - 151.

106 Complaint, ¶ 148.

107 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, pp. 7-9.

Speakers cannot be selected "based on an explicit or implicit understanding, hope, or desire that they will prescribe, purchase, or recommend Gilead products." Similarly, Gilead requires that advisors "must be selected based on their qualifications and may not be selected to reward or induce the prescription, use, or recommendation of Gilead products. Appropriate selection criteria include a variety of experiences and considerations, such as: clinical expertise; treatment experience with diverse patient demographics…; research/publication experience…," etc.[108]

b. *The criteria for selecting participants should be directly related to the purpose of the service and the number of HCPs participating should be reasonably necessary to achieve the identified purpose of the service.*[109] Each year, Gilead reassesses the speaker requirement for the coming year and requires that "the number of participants invited to Speaker training… may not exceed the number of Speakers needed to satisfy the business need…" Furthermore, if a speaker has "demonstrated poor product knowledge and/or presentation skills," he or she is not eligible to present.[110] Additionally, Gilead requires that "the number and type of advisors must be consistent with the legitimate business purpose of the Advisory Meeting and designed to elicit meaningful input from each advisor."[111] Each year, Gilead identifies "the number and types of expected Advisory

[108] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 57 - 58, 66.

[109] This guideline applies to consultants, i.e., both advisory board participants and speakers. Duke, Elizabeth, *supra* note 98, p. 23738. PhRMA Guidelines, *supra* note 104, p. 8.

[110] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 66 - 67.

[111] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 56 - 57.

Meetings" in the forthcoming year during its "annual strategic planning process."[112] For each Advisory Meeting, Gilead requires a "written RFA [Request for Approval] that clearly identifies the legitimate business need for the meeting, objectives, invitee information, criteria for selecting advisors… and any other pertinent information."[113]

c. *HCPs participating in programs to train company sponsored speakers may be offered reasonable compensation for their time and reimbursed for reasonable travel, lodging, and meal expenses if the participants receive extensive training on the company's product or on a specific topic and if the training results in participants providing a valuable service to the company.* [114] Gilead allows speakers to "receive reasonable compensation at fair market value when they are trained in a live session… Gilead may reimburse Speakers for reasonable expenses associated with travel, lodging, and modest meals… Reimbursement for flights is limited to economy class; however, business class travel may be permitted for intercontinental flights that exceed six hours, if pre-approved by Business Conduct."[115]

d. *HCPs participating should have a written contract specifying the basis for payment with a legitimate need for the services clearly identified.* [116] Gilead

---

[112] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 55.

[113] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 61.

[114] This guideline is specific to speakers. PhRMA Guidelines, *supra* note 104, p. 9.

[115] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 69.

[116] This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, at p. 8; Duke, Elizabeth, *supra* note 98, p. 23738.

requires that "Speakers may be compensated consistent with the fair market value of services provided, as set forth in their Speaker Agreement… [which must be] approved in advance by Business Conduct before participating in the Speaker Bureau."[117] Similarly, Gilead requires that an "advisor must sign an advisor agreement (approved by Business Conduct or the Legal Contacts Group) before attending an Advisory Meeting."[118] That agreement "must describe the Advisor's services and compensation. Compensation must reflect fair market value for the services provided."[119]

e. *The pharmaceutical company should maintain records of services provided by HCPs.* [120] Gilead requires that Marketing "maintain[] copies of other documents associated with the Speaker Bureau and Speaker Programs, including but not limited to: annual Speaker Bureau plans, Speaker biographies, PRC-approved presentations, Speaker training slide decks, quarterly Speaker reports, lists of all HCP attendees, invitation templates, and evaluation forms."[121] For advisory meetings Gilead instructs that "[a]ll documents related to Advisory Meetings must

---

117 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 67, 79. *See, e.g.*, Danny Chu 2013 Speaker Agreement, Gilead_Purcell_00006540; Paul Gaglio 2018 Speaker Agreement, Gilead_Purcell_00125932; Calvin Pan 2018 Speaker Agreement, Gilead_Purcell_00276425; Jianjun Li 2017 Speaker Agreement, Gilead_Purcell_00127928; Natarajan Ravendhran 2015 Speaker Agreement, Gilead_Purcell_00129801.

118 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 58.

119 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 58. See e.g., Calvin Pan 2014 Advisory Agreement, Gilead_Purcell_00222770; Danny Chu 2013 Advisory Agreement, Gilead_Purcell_00220104; Paul Gaglio 2017 Advisory Agreement, Gilead_Purcell_00219493; Jianjun Li 2013 Advisory Agreement, Gilead_Purcell_00221712; Natarajan Ravendhran 2014 Advisory Agreement, Gilead_Purcell_00223466.

120 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, at p. 8.

121 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 67.

be archived," including lists of attendees, sign-in sheets, meeting summaries, approved RFAs, invitation templates, a copy of expense forms, and advisor agreements.[122]

f. *HCP compensation or reimbursement should be reasonable and reflect a fair market value. Companies should have a maximum payment amount for speaking arrangements.* [123] Gilead speakers and advisors may be compensated in alignment with fair market value of services provided and remuneration cannot be based on prescribing habits or intent to induce or reward prescribing Gilead products.[124] Furthermore, Gilead limits "total annual compensation that may be paid to an individual HCP in connection with Speaker training and Speaker Programs [to] $100,000 total across all therapeutic areas," not including reimbursement for expenses incurred.[125] Additionally, for meal reimbursement and educational items Gilead upholds a "$2,000 annual aggregate spending limit per HCP" including attendee meals at Speaker Programs.[126]

g. *Programs should be held in appropriate venues, conducive to sharing information. These venues should not include resorts.* [127] Speaker trainings, speaker programs, and advisory boards all "must be held in locations that are conductive to business meetings" and "should not be selected based upon the

---

122 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 57.

123 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, s*upra* note 104, at pp. 8, 10; Duke, Elizabeth, *supra* note 98, at p. 23738.

124 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 59, 69, 79.

125 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 79.

126 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 36.

127 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, at pp. 8-10.

existence or quality of amenities […] ,but rather upon the proximity to attendees or transportation, quality and cost of meeting rooms […] and other business-related factors." Gilead even references the PhRMA guidelines noting that "Hotel accommodations should not be rated higher than four stars, should not be a resort, and must be consistent with the relevant provisions described in the PhRMA Code on Interactions with Healthcare Professionals."[128] Gilead further specifies that speaker programs need to be held in a separate room or defined area free from distractions if the venue is a restaurant or other public setting and that attendees should be able to hear and see the presenter easily and that the setup should facilitate engagement for attendees with the presentation.[129]

h. *Companies should have internal policies surrounding appropriate utilization of speakers and appropriate number of engagements per speaker.* [130] Speakers "must present an average of at least one Speaker Program for every six months of a contract year" and "Professional Speakers must provide at least two Speaker Programs to professional audiences, even if they are also contracted as Community Speakers."[131] Gilead's marketing department monitors speaking arrangements through Speaker Utilization Reports; speakers who demonstrate poor product knowledge and/or presentation skills, who have asked to be removed from the speaker bureau, who are no longer licensed to practice, or who have

---

128 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 60, 69, 79 - 80.

129 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 80.

130 This guideline applies to speakers. PhRMA Guidelines, *supra* note 104, at p. 10.

131 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869 pp. 64 - 65.

violated their contract or behaved in a manner that is inconsistent with Gilead policies are not eligible to present at a speaker program.[132]

i. *Speakers and their materials should clearly identify the company that is sponsoring the presentation.* [133] Gilead outlines that a Speaker "should clearly identify that Gilead is sponsoring the presentation, [and that] the Speaker is presenting on behalf of Gilead."[134]

j. *Recreational activities or entertainment should not be in conjunction with events.*[135] Gilead specifies that for speaker programs and advisory meetings "[e]ntertainment and recreation may not be provided."[136]

k. *Honoraria and travel or lodging expenses should not be reimbursed for non-participating HCP attendees.* [137] If a speaker elects to bring a guest when traveling for speaker training or speaker programs, "Gilead will not pay for any incremental expenses incurred by the guest, including travel, entertainment, or meals [and] [g]uests may not attend Speaker training sessions" or the presentation.[138] Similarly, Gilead does not allow lodging or other expenses attributed to guests of advisory board participants to be reimbursed.[139]

---

132 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 67.

133 This guideline applies to speakers. PhRMA Guidelines, *supra* note 104, at p. 10.

134 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 77.

135 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, at p. 9; Duke, Elizabeth, *supra* note 98, at p. 23738.

136 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 60, 69, 80.

137 This guideline applies to consultants, i.e., both advisory board participants and speakers. PhRMA Guidelines, *supra* note 104, at pp. 9, 25-26, 28; Duke, Elizabeth, *supra* note 98, at pp. 23738.

138 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 69, 80.

139 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 80.

B. Gilead honoraria payments for speaking and advisory board programs were at or below fair market value

75. As explained above, OIG has issued guidance that "fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern."[140] Based on my assessment of Gilead's honoraria payments made to physicians for participation in its speaker and advisory board programs, the payments were at or below fair market value.

76. As a matter of economics, compensation is considered to be at Fair Market Value ("FMV") if it reflects the objective market rate a physician would receive if his or her time were spent caring for patients, adjusted with a premium that reflects the diminishing marginal utility of the physician's time and for providing services outside of typical work responsibilities.[141] Because average physician salaries vary by specialty and experience, the FMV for physicians providing the same service will also vary.

77. An FMV calculation consists of a number of steps. The first step is to determine average hourly physician salaries for relevant specialties and experience levels, which can be done using objective physician compensation survey data.[142] An additional "expertise" premium will be added for physicians with higher influence, such as regionally or nationally recognized physician educators, and a "utility" premium may also be added to compensate physicians for services outside of their normal work responsibilities, often disrupting time spent with family or

---

[140] Duke, Elizabeth, *supra* note 98, at p. 23738.

[141] Based on my experience and that of colleagues at multiple medical centers, it is typical for physicians to be compensated at higher rates for off-hours work (e.g., late afternoons into early evenings, nights, and weekends).

[142] *See, e.g.,* Eaton, Fred and Jaimee Reid, "Mirror, Mirror on the Wall—Evaluating Fair Market Value for Manufacturer-Physician Consulting Arrangements," Food and Drug Law Journal, 2010, Vol. 65(1), pp. 141-158, at pp. 155-156. *See also*, Ferrari, Andrea M., Ann Brandt, and Scott Safriet, "Determining 'Fair Market Value' for Physician Consulting Services: The New 'Big Question' for Life Sciences Companies," *The American Health Lawyers Association Life Sciences Practice Group*, 2009, Vol. 3(1), pp. 9-13.

engaging in other non-professional activities (collectively, "premium"). Finally, the FMV compensation for a specific event will be the product of the physician hourly rate (i.e., hourly salary multiplied by the premium) and the amount of time required for the event, including for preparation and travel. Based on my experience as a physician and an economist, this is an appropriate framework to accurately capture the FMV for an event participant's time.

78. Gilead's methodology to calculate FMV compensation is generally consistent with the approach I outline above. It has a reasonable economic basis, utilizes transparent calculations, and is based on objective data from multiple sources. Gilead [redacted]

[143] Gilead_Purcell_00338915, p. 6; *See also*, Gilead_Purcell_00337137, p. 1.

[144] Gilead_Purcell_00000802, p.12. [redacted]

[redacted].[147]

79. For speaker programs, Gilead's honoraria payments are detailed in individual speaking agreements with the speakers who participate in its programs. Each agreement details the total honoraria to be paid, and the basis for such honoraria. For example, [redacted]

145 Gilead_Purcell_00000802, pp. 22 – 23.

146 Gilead_Purcell_00000802, pp. 19 – 23.

147 *See, e.g.*, Gilead_Purcell_00217702, p. 1, [redacted].

148 [redacted]

149 Gilead_Purcell_00005461, p. 9.

150 Gilead_Purcell_00000802, pp. 20-22.

151 Gilead_Purcell_00338915, pp. 7, 10.

[redacted]

80. For advisory boards, Gilead's honoraria payments are detailed in individual advisory agreements with the advisors who participate in that specific program, which are signed prior to each advisory board. For example, [redacted]

81. Current and former Gilead employees also testified that they believed the honoraria payments to HCPs were consistent with a fair market value. David Johnson, Gilead's former VP, Sales & Marketing, Liver Disease BU, testified that speakers were paid a rate that varied based on fair market value, and that this value was determined by "a team that was led by legal, and an external vendor that specialized in fair market value for the industry."[156] Similarly, Leilani Larson, Gilead's current Senior Director, HBV Marketing, testified that advisory board compensation is "determined by the fair market value calculator that was established by

---

152 [redacted]

153 Gilead_Purcell_00217702, p. 1.

154 Gilead_Purcell_00338915, pp. 7, 10.

155 [redacted] Gilead_Purcell_00217702; Gilead_Purcell_00134580.

156 Transcript from Deposition of David Johnson, August 31, 2020, pp. 9:21-23, 33:19-24, 109:14-110:8.

[Gilead's] business conduct team" and that Gilead's policies would not permit disregarding the fair market value calculator and paying the HCP a different amount.[157] Furthermore, Gilead had caps on the honoraria a speaker could receive, which Relator Groome testified were the same as those of her former employer Portola Pharmaceuticals.[158] Relator Groome further testified that Portola Pharmaceutical's method of paying speakers was consistent with a fair market value.[159]

82. Based on Gilead's reported FMV calculation methodology and my review of selected speaker and advisor agreements, I find that Gilead's compensation for speaking and advisory board events is generally consistent with an economically reasonable and objective FMV calculation, and compensates physicians appropriately for their time.

C. Gilead speakers and advisors had extensive experience in treating patients with HBV

83. Consistent with OIG and PhRMA guidelines, Gilead's speakers and advisors had appropriate expertise, reputation, knowledge and experience.

84. Prescription-writing of Viread®, Vemlidy®, and other antiviral medications to treat HBV is concentrated among a small subset of high volume prescribers who are typically also recognized physician educators (see Exhibit 4). There are, however, many physicians who prescribe these products at much lower levels. This disparity is largely driven by the fact that HBV is most effectively treated by specialists (gastroenterologists and hepatologists), but often ends up being treated by primary care physicians or other physicians instead (such as an infectious disease doctor).

---

157 Transcript from Deposition of Leilani Larson, September 4, 2020, pp. 20:9-12, 50:1-20.

158 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 79; Transcript from Deposition of Kimberly Groome, April 10, 2021, pp. 337:19-338:4. *See also* Portola Policy on Promotional Speaker Programs, PPI0042.

159 Transcript from Deposition of Kimberly Groome, April 10, 2021. pp. 351:5-352:3.

Excerpt of Exhibit 4[160]

85. For example, from 2013 - 2019, [redacted]. The Hepatitis B Foundation advises HBV patients that "[g]astroenterologists and hepatologists are the experts in the liver. It is recommended that individuals living with Hepatitis B see a hepatologist but if this is not possible, a knowledgeable primary care doctor should be able to monitor you."[161] Indeed, per Exhibit 5, while hepatologists and gastroenterologists prescribe the most Viread® and Vemlidy® prescriptions on a quarterly basis, two of the most common specialists prescribing Viread® or

[160] Each dot represents a prescriber. The average quarterly total Viread® and Vemlidy® prescription calculation excludes quarters where prescribers had no prescriptions. Gilead_Purcell_00224639, Gilead_Purcell_00311272, Gilead_Purcell_00224639, Gilead_Purcell_00327018, Gilead_Purcell_00340769 ("IMS/IQVIA Prescription Data").

[161] "How To Talk To Your Doctor About Hep B in 5 Minutes," *Hepatitis B Foundation*, November 13, 2019, available at https://www hepb.org/blog/talk-doctor-hep-b-5-minutes/.

Vemlidy® are primary care and internal medicine doctors (a common specialty for primary care physicians). [redacted]

[redacted].[162]

Excerpt of Exhibit 5[163]

[redacted]

[162] Specialties were available for [redacted]. Gilead_Purcell_00046904, 00058651, 00075800, 00109300, 00109542, 00109677, 00109731, 00114455, 00114779, 00137107, 00216770, 00216771, 00216772, 00216774, 00224964, 00279007, 00283133 ("Managed Care Report Data"); Speaker Program Spend Reports; Advisory Board Spend Reports.

[163] Averages across quarters per prescriber were used for years when combining yearly files with overlapping date ranges. Average quarterly prescriptions by specialty is calculated by taking the mean of the quarterly total prescriptions for all physicians within that specialty. [redacted]
Managed Care Report D

86. Amongst other criteria, Gilead's Business Conduct Manual requires that members of its Speaker Bureau have "clinical expertise in the relevant therapeutic area and/or product category,"[164] and that the "type of advisors must be consistent with the legitimate business purpose of the Advisory Meeting."[165] Indeed, many of Gilead's OLP participants [redacted] over the at-issue period had extensive research, publishing, and teaching experience. For example:

- Dr. Calvin Pan, the physician in the OLP [redacted] over the at-issue period, is a gastroenterologist specializing in HBV at NYU Langone Health. He is also a clinical professor at NYU Grossman School of Medicine.[166] He has hundreds of publications, many of which are directly related to HBV. Additionally, he has completed numerous studies on the safety and efficacy of Viread® and Vemlidy®, as well as studies that evaluate the effectiveness of entecavir, telbivudine, and lamivudine.[167] Notably, Dr. Pan also received substantial speaker payments from

---

164 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 66.

165 *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 56.

166 Calvin Q. Pan: About Me, NYU Langone, available at https://tinyurl.com/zhsjsy9t.

167 *See, e.g.,* Pan, C.Q, et al. "Response to tenofovir monotherapy in chronic hepatitis B patients with prior suboptimal response to entecavir,*" Journal of Viral Hepatitis,* October 17, 2011, vol. 19(3)*; See e.g.,* Lu, Louis, Yip, Benjamin, Trinh, Huy, Pan, Calvin Q., et al. "Tenofovir-based alternate therapies for chronic hepatitis B patients with partial virological response to entecavir," J*ournal of Viral Hepatitis,* August 22, 2015, vol. 22(8); Tong MJ, Pan CQ, Hann HW, et al., "The management of chronic hepatitis B in Asian Americans," *Digestive Diseases and Sciences,* September 21, 2011, vol. 56, (11); Pan, Calvin Q, and Hannah M Lee, "Antiviral therapy for chronic hepatitis B in pregnancy," *Seminars in Liver Disease,* June 8, 2013, vol. 33(2); Pan, Calvin et al., "Improvement in liver histology among Asian patients with chronic hepatitis B after long-term treatment with entecavir," *Liver International,* January 25, 2013, available at https://pubmed ncbi.nlm.nih.gov/23489906/.

Bristol-Meyers Squibb (the manufacturer of Baraclude) in 2013 and 2014 prior to generic availability in late 2014.[168]

- Dr. Danny Chu, the physician in the OLP [redacted] over the at-issue period, is also a gastroenterologist at NYU Langone Health and a clinical professor at NYU Grossman School of Medicine. He has numerous publications focused on HBV, including a case report describing liver failure caused by Vemlidy®.[169] Dr. Chu also received speaker payments from Bristol-Meyers Squibb related to Baraclude in 2013.[170]
- Dr. Jianjun Li, the physician in the OLP [redacted] over the at-issue period, is currently the head of New York & New Jersey Gastroenterology Associates, and from 2004 to 2011 was the director of the Division of Gastroenterology and Hepatology at Maimonides Medical Center. He also serves as a clinical professor at SUNY Downstate College of medicine and has been nominated for numerous awards, including "The Best Gastroenterologist in America."[171] Dr. Li also received speaker payments from Bristol-Meyers Squibb related to Baraclude in 2013 and 2014.
- Dr. Paul Gaglio, another frequent OLP speaker [redacted], is a transplant hepatologist and the director of Hepatology Outreach at New York

---

168 Open Payments Data, available at https://openpaymentsdata.cms.gov/physician/246278; *See also*, "Teva Announces Launch of Generic Baraclude® Tablets, 0.5mg and 1mg, in the United States," *Teva*, September 4, 2014, available at https://www.tevapharm.com/news-and-media/latest-news/teva-announces-launch-of-generic-baraclude-tablets-0.5mg-and-1mg-in-the-united-states/.

169 Chu, Danny, et al., "Tenofovir Alafenamide (TAF) Induced Liver Failure," *Gut and Gastroenterology,* 2018, available at http://sciaeon.org/articles/Tenofovir-Alafenamide-(TAF)-Induced-Liver-Failure.pdf.

170 Open Payments Data, available at https://openpaymentsdata.cms.gov/physician/267273.

171 Dr. Jianjun Li MD, New York & New Jersey Gastroenterology Associates, https://www.ny-njgastro.com/lijianjun.html.

Presbyterian Hospital. He specializes in viral hepatitis and has numerous publications on the topic. He has been the recipient of numerous honors, including "Best Doctors® in America," fellowships in several liver and gastroenterology associations, and a teaching award at Tulane University.[172]

- Dr. Natarajan Ravendhran, another frequent OLP speaker [redacted], is a gastroenterologist and president at Digestive Disease Associates, which is affiliated with several hospitals in Maryland.[173] He is the Chief of the Department of Gastroenterology at St. Agnes Hospital and is involved with several clinical trials studying hepatitis B & C.[174] He also has many publications, most of which concentrate on viral hepatitis.[175]

87. These individuals are at the top of their fields and have extensive experience treating patients with HBV, as well as conducting research on a range of HBV treatments. While all of the speakers prescribe Viread® and Vemlidy®, they also prescribe other HBV medications and have wide variation in the average number of prescriptions they write each quarter. Per Exhibit 6, [redacted]

[172] Paul J. Gaglio, Columbia Surgery, https://columbiasurgery.org/paul-j-gaglio-md-facp.

[173] Natarajan Ravendhran, Digestive Disease Associates, https://www.ddamd.com/natarajan-ravendhran-m-d/.

[174] Natarajan Ravendhran, MD, MedicineNet, https://www.medicinenet.com/doctors/0a9169a9-c5db-4ea9-b8ae-20b010d4f969/natarajan-ravendhran/eldersburg-md_doctor htm.

[175] List of Publications by Ravendhran N, PubMed, https://pubmed.ncbi nlm nih.gov/?term=Ravendhran%20N&cauthor_id=30980576&page=2.

[redacted].[176] This wide variation in prescribing volume, while remaining uniformly qualified, demonstrates that Gilead selects speakers and advisors based on their qualifications and experience, not because of their volume of Gilead prescriptions.

Excerpt of Exhibit 6[177]

[redacted]

[176] The Managed Care Report Data demonstrate that the speakers [redacted] *See* Managed Care Report Data; Speaker Program Spend Reports.

[177] I am unaware of any additional payment data, but reserve the right to update my analyses if additional data become available. This note is relevant for all analyses based on payment data. The [redacted] HCPs were identified based on the total payments and reimbursements from AHM speaker programs, non-AHM programs (primarily speaker trainings), and advisory board programs from 2013-2019. Speaker Program Spend Reports; Advisory Board Spend Reports; IMS/IQVIA prescription Data.

D. Gilead maintained strict meal spending limits for speaker and advisory board programs

88. In accordance with OIG and PhRMA guidelines, Gilead imposed strict rules related to meal and travel expenses for speaker programs and advisory boards – a further indicator that Gilead's programs were inconsistent with "sham" events designed to improperly influence physicians' prescriptions. According to Gilead's Business Conduct Manual, the maximum meal spending limit per physician ranged from $35 per physician for in-office breakfast, snack, or lunch up to $125 per physician for dinners outside the office.[178] Gilead personnel were only allowed to pay for travel and lodging accommodations for "bona fide consulting, speaking, or investigator services," which means speaker program attendees were not reimbursed for any travel or lodging associated with attending Gilead speaker events.[179]

89. The vast majority of Gilead's in-kind meal payments for speaker programs and advisory boards were within these guidelines. For example, the average total in-kind payments to speaker event attendees was low - $97 over the full period, with only 3.4 percent exceeding the $125 limit.[180] Similarly, for advisory board programs the majority of meals were at or under $125 at more than 90 percent of events; all of the events that exceeded the limit occurred in

---

[178] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 38. Breakfast, snack, and lunch meals outside the office had a limit of $50 per HCP, as did dinner meals in-office.

[179] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 43 ("Gilead may pay or reimburse expenses incurred in connection with bona fide consulting, speaking, or investigator services, including reasonable travel and accommodations. In all other circumstances, Gilead Personnel may not pay for transportation and/or lodging."), p.80 ("Gilead will neither pay compensation nor reimburse expenses for attendees.").

[180] Events that exceeded the $125 limit were out of office programs, most of which occurred in 2013.

2013.[181] Notably, all in-kind meal payments were below the FMV for a single hour of a time for any of the physician specialties discussed in Section V.B.

90. Consistent with Gilead's policy to avoid "venues that are luxurious or have a reputation for being luxurious based on local standards,"[182] Gilead frequently held speaker events in physician offices - a venue that is remarkably un-luxurious. Per Exhibit 7, from 2013 to 2019, [redacted]. These in-office events typically had significantly lower per-attendee spending, with the majority of events spending less than $20 per attendee.

Excerpt of Exhibit 7[183]

[redacted]

[181] The majority of meals were within the $125 limit at 85 out of 98 advisory board programs. To note, at four of these 85 events, the meal spend exceeded $125 for a small number of participants, while meals for all other participants were within the $125 limit. Advisory Board Spend Reports.

[182] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 80.

[183] Limited to completed AHM speaker events. Speaker Program Spend Reports.

91. For speaker events held out of office, Gilead imposed strict per-person spending limits and diligently investigated events that exceeded those limits.[184] 97 percent of all Gilead speaker events had per-attendee spend at or less than the company's $125 per person limit. For events that exceeded this limit, Gilead investigated the instance and maintained clear documentation of the events and the reason for exceeding the spending limit. [185] Relator Groome testified to Gilead's enforcement of the meal spending limit confirming that this rule of the Business Conduct Manual was followed and enforced and that she would receive an email notifying her of any meals that violated the $125 limit.[186] Most events that exceeded the $125 per person spending limit did so due to unexpected changes between expected and actual attendance at the event. Indeed, as Exhibit 8 demonstrates, when average spending per attendee is calculated based on expected attendance rather than actual attendance, the share of events exceeding the $125 limit falls to just over 1 percent.

[184] For breakfast or lunch held out of office Gilead imposes a limit of $50 per HCP and a limit of $125 per HCP for dinner out of office. All meals must be modest and provided in connection with a legitimate business purpose. Gilead instructs that employees report any violation of policies and that "each violation will be considered on a case-by-case basis, taking into account all relevant factors to determine the appropriate response" when investigating policy violations. Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, pp. 2- 4, 37-38.

[185] *See, e.g.,* Gilead_Purcell_00317672, Gilead_Purcell_00132285.

[186] Transcript from Deposition of Kimberly Groome, April 10, 2021, pp. 341:12-25, 342:1-4. ("This was an actual business conduct manual rule that was followed and enforced? A. The meal cap, yes.")

Excerpt of Exhibit 8[187]

92. Gilead Executive Territory Supervisor Graham Warden provided testimony illustrating Gilead's commitment to strictly adhere to the meal spend limit. Warden explained that when the meal bill was $3 over the total budget, about $0.16 over per person, AHM reported it to Warden's boss after reviewing the receipt.[188] Warden's boss emailed Warden to address the issue and followed up with AHM.[189]

93. Gilead's spending limits are also consistent with literature outlining how to ethically engage with physicians over meals. In a 2017 survey of pharmaceutical meeting

[187] 

[188] Transcript from Deposition of Graham Warden, September 23, 2020, pp. 14:3-9, 300:13-24, 301:1-8.

[189] Transcript from Deposition of Graham Warden, September 23, 2020, p. 301:1-14.

managers, respondents noted average meal caps of $61 for breakfast, $70 for lunch, and $125 for dinner, which is the same as Gilead's limit for dinner but higher for breakfast and lunch.[190] Additionally, in a 2015 paper discussing the ethics of professional speaker events with meals, David F. Essi provided examples of meal spending guidelines, noting that "[s]pending per healthcare provider (HCP), including tax and gratuity, cannot exceed $125," which is again consistent with Gilead's out-of-office dinner spending limit.[191]

94. For a specific point of comparison, [redacted].[193] Gilead's own $125 per person dinner spending limit [redacted]. After adjusting for expected attendance, only 6 of Gilead's nearly 3,000 out of office professional events [redacted]. Gilead's $35 per person in-office spending limit for breakfast/snack/lunch [redacted],[194] and over 97 percent of Gilead's in-office events did not exceed $35 per person in spending, [redacted]

95. Given Gilead's strict spending policies, which typically result in minimal in-kind payments to attendees, it is perhaps unsurprising that [redacted]

---

190 Pelletier, Sue, "Take a Sneak Peek at Pharma Planner Meal Cap Survey Results," *MeetingsNet*, January 18, 2017, available at https://www meetingsnet.com/pharmaceutical-meetings/take-sneak-peek-pharma-planner-meal-cap-survey-results.

191 Essi, David F., "Mixing Dinner and Drugs—Is It Ethically Contraindicated?" American Medical Association Journal of Ethics, August 2015, Vol. 17(8), pp. 787-795, at p. 788.

192 Portola Pharmaceuticals was purchased by Alexion in July 2020. See "Alexion Completes Acquisition of Portola," *Alexion*, July 2, 2020, available at https://ir.alexion.com/news-releases/news-release-details/alexion-completes-acquisition-portola.

193 [redacted] at 021-022.

194 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 38.

[redacted]. While these [redacted] were likely a mix of both non-prescriber HCPs and HCPs with prescribing ability that chose not to prescribe Viread® or Vemlidy®, Gilead nonetheless found it valuable to invest in their HBV education regardless of whether they had written Gilead prescriptions in the past or could or would write them in the future. This is further evidence that Gilead's intended purpose in hosting these events was to educate attendees on the disease state and HBV treatment options, and not to influence prescribing activity.

96. Taken as a whole, there is no indication that Gilead's event spending on attendees was designed to provide the type of luxurious and inappropriate kickback that OIG's and Gilead's internal guidelines prohibited.

E. Attendance at speaker and advisory board programs was appropriate for the events' intended purpose

97. With respect to advisory board programs, beginning in 2014, Gilead aimed "to have between 10 and 20 advisors in attendance… with a maximum of 20," but notes that "[i]f there are larger groups, there should be smaller breakout sessions."[195] Prior to 2014, the Business Conduct Manual did not include any explicit guidance on the targeted number of advisors for an advisory board program.[196] Exhibit 9 summarizes the number of advisors present at each program during the at-issue period. Of the 98 advisory board programs during the at-issue period, on average (median), there were 20 advisors present.[197] Only 11 events had fewer than 10

[195] *See, e.g.,* Gilead 2014 Business Conduct Manual, Gilead_Purcell_00000163, p. 65.

[196] *See*, *e.g.*, Gilead 2013 Business Conduct Manual, Gilead_Purcell_00000001, Section VI.5.

[197] Note that I excluded "faculty" from the advisor count where it was evident in the data, but case documents indicate that advisory boards often had 1-2 faculty members present who were included in the data but not clearly distinguished from advisors. *See, e.g.* Gilead_Purcell_00007306, p.70 (Danny Chu listed as presenter); Advisory Board Spend Report, Gilead_Purcell_00216563, EXP_EXPENSE_DETAIL_ID value of mrichardson20140507140759-63-63 (Danny Chu included with no indication of faculty); Gilead_Purcell_00316847, p. 4; Gilead_Purcell_00308704, p. 4.

advisors, and 4 of these had between six and nine advisors.[198] 48 events had more than 20 advisors, though 22 of these had 30 or fewer advisors.[199] Furthermore, I was able to locate the underlying materials associated with events where 20 or more advisors were present; these programs either occurred prior to 2014, or demonstrated clear indications of breakout sessions, which, after 2014, were required for events with more than 20 advisors present.[200] This suggests that most, if not all, of the advisory boards with more than 20 advisors present did so due to breakout sessions, consistent with Gilead's Business Conduct Manual.

Excerpt of Exhibit 9[201]

[198] Advisory Board attendance counts are based on honoraria payments reported in the Advisory Board Spend Reports. For certain events, such as the June 21, 2018 Specialty Pharmacy CHB Advisory Board, the data only indicate a single honoraria recipient (and thus a single advisor), but underlying materials indicate that nine additional advisors were present; these advisors were primarily non-prescribing PharmDs which may explain their absence from the data. *See, e.g.,* Gilead_Purcell_00285645.

[199] Advisory Board Spend Reports.

[200] *See, e.g.,* Gilead_Purcell_00007253, pp. 52 - 53; Gilead_Purcell_00007404, pp. 63 - 65; Gilead_Purcell_00007583, pp. 8 - 10, 14, 78 - 83.

[201] See note 42 for advisory board identification methodology. The number of advisors is based on the EXP_HCP_ID and hcp_id fields in the Advisory Board Spend Reports and is limited to attendees who received "Payment" based on the EXP_PURPOSE or exp_category fields. Faculty attendees were excluded when they were apparent in the data. Advisory Board Spend Reports.

98. With respect to speaker programs, Gilead held programs that targeted different audiences (professional programs for HCPs and community programs for community members), the vast majority of both types of speaker programs were very well attended. Gilead's attendance policy for speaker programs requires at least four invitees to confirm their attendance 48 hours before the program.[202] Thus, in the event of unexpected absences, a speaker program could take place with less than four attendees but still comply with Gilead's attendance policy. Relator Groome testified that Gilead did its best to follow and enforce the minimum attendee policy.[203] As shown in Exhibit 10, within the seven year period and [redacted], there were only 3 professional programs with zero attendees, and an additional 43 programs (approximately 1 percent) with 1-3 attendees, indicating that over 98 percent of events had four or more attendees. Similarly, per Exhibit 11, within the seven year period and [redacted], there were only 11 community programs with zero attendees, and an additional 16 programs (approximately 1 percent) with 1-3 attendees, indicating that over 97 percent had four or more attendees.[204] Furthermore, many of the community events were very highly attended, with a median of 50 attendees and up to 550, reflecting the value to the community of the information that Gilead provided at these events. Gilead professional events had a median of 10 attendees, and up to 151.

---

[202] *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 75. This policy is more conservative than Relator Groome's subsequent employer, Portola, which only requires expected attendance of 3. See PPI0044. Based on my experience, speaker programs with four (or fewer) attendees could certainly still provide educational value.

[203] Transcript from Deposition of Kimberly Groome, April 10, 2021, pp. 342:22-25, 343:1-15.

[204] Under Gilead's patient privacy policy, patient attendees at Community Programs are not required to identify themselves on sign-in sheets. Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 78.

Excerpt of Exhibit 10[205]

Excerpt of Exhibit 11[206]

99. In the Complaint, Relators assert that "inappropriate attendees, including 'Admins,' 'Others,' and 'Office Staff,'" demonstrate the "sham" nature of Gilead's OLP, because "[t]hese attendees could not prescribe Gilead's drugs and were an inappropriate audience for the topics the programs purported to cover."[207] From a physician's perspective, I believe the unique attributes of HBV make these individuals very important attendees. As discussed in Section III.A, HBV is a stigmatized disease that is chronically under diagnosed and under treated. Simultaneously, ample research has demonstrated the clinical value in educating populations at high risk for HBV, resulting in increased screening and treatment and decreased transmission.[208] Non-prescribing physician office staff can play a key role in providing information to patients, whether it be pointing them towards educational events or screenings. This has been well documented in diabetes care, for example, but is equally relevant for HBV patients. In a 2006 study, researchers found that a program that provided two hours of basic diabetes education for clinical staff with subsequent ongoing support resulted in increased patient and staff confidence, improved patient health markers, and higher patient-reported quality of

205 [redacted]

206 [redacted]

207 Complaint, ¶ 156; *See also*, Complaint ¶ 173.

208 *See, e.g.,* Shah, Hemant, et al., *supra* note 13, at p. 922 ("Simple educational interventions for patients with HBV or HCV infection significantly increase patients' knowledge about their disease. More complex, multimodal educationa interventions seem to cause behavioral changes that increase rates of testing, vaccination (for HBV), and treatment… Delays in identifying disease status can result in increased likelihood of virus transmission to others, limited treatment options, and worsened patient outcomes.").

life.[209] Similarly, a 2013 study found that "with minimal training, [medical office staff] can effectively reduce the burden of [encouraging routine tests and screening] on PCPs, help to ensure that high-quality diabetes care is delivered, and increase patient awareness of the importance of this care. Such training can empower [medical office staff] to be active members of the health care team."[210] Given that many studies have shown lack of communication and follow-up as a key reason for under-screening high risk HBV populations,[211] education of medical office staff would add substantial value in addressing these problems.

100. Under Gilead's policies, office staff involved in patient care were part of the continuum of care. The Business Conduct Manual sets out the following definition for HCP: "HCPs include persons who are part of the continuum of patient care, including but not limited to physicians, nurse practitioners, physicians assistants, nurses, pharmacists, laboratory and other medical technicians, counselors, case managers, treatment educators, and executives responsible for decision making within hospitals, clinics, pharmacies, and managed care entities. HCPs do not include medical office staff who are not involved in patient care (such as receptionists and billing clerks)…"[212] For professional speaker programs, Gilead required that invitations "state

---

209 Celeste-Harris, Sonya, et al., "Educating Medical Office Staff: Enhancing Diabetes Care in Primary Care Offices," *American Diabetes Association, Diabetes Spectrum,* April 2006, Vol. 19(2), pp. 84 - 89, available at https://spectrum.diabetesjournals.org/content/19/2/84.

210 Maryniuk, Melinda D., et al., "Enhancing the Role of Medical Office Staff in Diabetes Care and Education," *American Diabetes Association, Clinical Diabetes*, July 2013, Vol. 31(3), pp. 116 - 122, at p. 117, available at https://clinical.diabetesjournals.org/content/31/3/116.

211 *See, e.g.,* Chao, Stephanie, et al., "The Jade Ribbon Campaign: A Model Program for Community Outreach and Education to Prevent Liver Cancer in Asian Americans," *Journal of Immigrant and Minority Health*, December 2007, Vol. 11(4), pp. 281 - 290, available at https://www researchgate net/publication/5856798_The_Jade_Ribbon_Campaign_A_Model_Program_for_Community_Outreach_and_Education_to_Prevent_Liver_Cancer_in_Asian_Americans.

212 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, at pp. 1 - 2 (emphasis added).

that, in accordance with the PhRMA Code, attendance is limited to HCPs, and that spouses and guests of these HCPs may not attend."[213]

101. Gilead employees, such as territory supervisor Peter Wu (who also worked at Portola with Relator Groome) also recognize the value of having office staff at speaker programs; when asked about specific attendees at an HBV speaker program, Mr. Wu replied, "[t]hese individuals are office managers who are involved in benefits investigation, insurance coverage, prior authorization, appeals process, scheduling labs, providing patient disease state and medication info, and referring them to the GI's as appropriate. They are part of the continuum of care in hepatitis B."[214] Graham Warden reiterates that it's important for other office staff to be educated about HBV since, for example, a receptionist "might be handling insurance, that receptionist might be taking to the patients or taking call-backs from the patients when they're asking about their drug" and therefore would benefit from attending a speaker program.[215] Learning about HBV transmission and disease progression is important for all office members since many of the associated practices see more than 20 or 30 percent of their patient population with HBV.[216] Similarly, Leilani Larson testified that "[p]ersons in the continuum of care may be…anybody who has contact with the patient that comes into an office," including a receptionist, and based on Gilead's policies receptionists would thus be appropriate attendees at speaker programs.[217]

---

213 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, at p. 74.

214 Gilead_Purcell_00200500.

215 Transcript from Deposition of Graham Warden, September 23, 2020, p.63:1-15.

216 Transcript from Deposition of Ilija Zlatar, November 11, 2020, pp. 214:4-25, 215:1-17.

217 Transcript from Deposition of Leilani Larson, September 4, 2020, pp. 61:8-25, 62:1-3.

102. Other physicians support this perspective and note the specific relevance for HBV. For example, Dr. Calvin Pan, one of Gilead's top speakers, testified that office staff who "know the medications side effects they could talk to the patient and correct the information whether they have the side effects during the treatment, and if they understand what might be the monitor algorithm, they could remind patients when they should come back for follow up."[218] He further testifies that "many of the patients education and follow up enforcement of the medication are adherence relates to the rely on the staff [*sic*] … [a]nd many other studies are showing the more coaching more discussion with your patients can enhance the compliance."[219] This is especially relevant for HBV patients, because "70 percent of hepatitis B patients they are first generation of immigrants. They have language barrier, and they are there for many offers [*sic*] in Asian community they have to leverage their staff to educate and explain to their patients because the patient will not be able to get the other medical knowledge or resources outside of the community providers." [220]

103. Additionally, Relators allege numerous "sham" events due to the presence of family members, but the data do not support these allegations. For example, Relators point to an August 21, 2019 event "scheduled in conjunction with an association of Vietnamese-American Pharmacists and was attended by forty (40) people almost entirely made up of pharmacists and pharmacy staff, many of whom had the same last name suggesting they were family members. In fact, fourteen (14) attendees had the exact same last name."[221] The fourteen attendees Relators

---

[218] Rough Transcript from Deposition of Calvin Pan, April 22, 2021, p. 237:22-238:5.

[219] Rough Transcript from Deposition of Calvin Pan, April 22, 2021, p. 238:8-238:23.

[220] Rough Transcript from Deposition of Calvin Pan, April 22, 2021, p. 237:2-9.

[221] Complaint, ¶ 165.

reference here all had the last name "Nguyen." Not only is the surname Nguyen the most common last name for Asians and Pacific-Islanders in the U.S.,[222] but it is also the most common Vietnamese surname, accounting for 30 to 40 percent of the Vietnamese population.[223] Given that this event was put on in conjunction with the association of Vietnamese-American pharmacists and had 40 attendees, one would expect between 12 and 16 attendees with this last name, matching the 14 nearly perfectly. Furthermore, *none* of these attendees resided at the same address. As a result, there is no reason to believe based on the attendance data that the attendees with the last name Nguyen were all members of the same family.[224]

104. Finally, Relators further allege that certain events were illegitimate due to the presence of attendees who were trained speakers for the same topic.[225] For example, Relators state that on July 18, 2019 Dr. Xiaoli Ma, a Gilead trained speaker, attended an event despite the fact that "Gilead's policy prohibits trained speakers from attending programs on topics for which they are also speakers."[226] From a physician's perspective, attending a presentation on the same topic that you are going to speak about has substantial value. Each physician has unique experiences with different patients. Hearing about these experiences, perceptions, and lessons from other physicians is the very purpose of such speaker programs, and can provide valuable points of reference for your own future presentation. Indeed, Dr. Ma attended the July 2019 presentation *before* he spoke himself on the same topic on August 19, 2019, providing him a

---

222 "Most common last names for Asian and Pacific Islanders in the U.S.," *Name Census*, available at https://namecensus.com/data/asian_pacific_islander.html.

223 Nosowitz, Dan, "Why 40% of Vietnamese People Have the Same Last Name," *Atlas Obscura*, March 28, 2017, available at https://www.atlasobscura.com/articles/nguyen-name-common-vietnam.

224 IQV-Gilead-092879, attendees for meeting ID INT-0025004.

225 Complaint, ¶ 160.

226 Complaint, ¶ 160.

potentially valuable opportunity to learn about another physician's experiences before he presented.[227]

VI. THERE IS NO EVIDENCE THAT GILEAD'S PAYMENTS TO HCPS INFLUENCED PRESCRIBING BEHAVIOR

105. Relators allege that Gilead paid HCPs honoraria through the OLP to induce Viread® and Vemlidy® prescribing. I understand that payments made to HCPs at fair market value for legitimate services are lawful and, in my experience, are common practice in the pharmaceutical industry (see Section IV). Thus, it cannot be assumed that all honoraria paid to HCPs were illegal kickbacks, or that every prescription an HCP writes after receiving honoraria was a false claim for reimbursement under the FCA.

106. From an economic perspective, damages occur when one party (e.g., Medicare or Medicaid) pays more than they would have absent some alleged conduct (e.g., a kickback payment). In order to determine whether economic damages exist, it must first be determined if the at-issue payments were in fact kickbacks. If a physician's prescribing is not impacted by the allegedly improper payment, then it calls into question whether that payment was truly improper. Rather, it may be that the payment was appropriate given the specifics of that physician.

107. An HCP's decision to prescribe a particular medication to an HBV patient is highly complex and individualized. For example, HCPs consider whether the patient suffers from comorbidities, such as HIV, is at higher risk for certain side effects (e.g., kidney damage), and what medications, if any, have already been tried. HCPs also reference many different sources for up-to-date information regarding available treatments, such as literature, clinical trial results, clinical guidelines, peers' prescribing experiences, and their own prescribing experiences. HCPs

[227] Speaker Program Spend Reports.

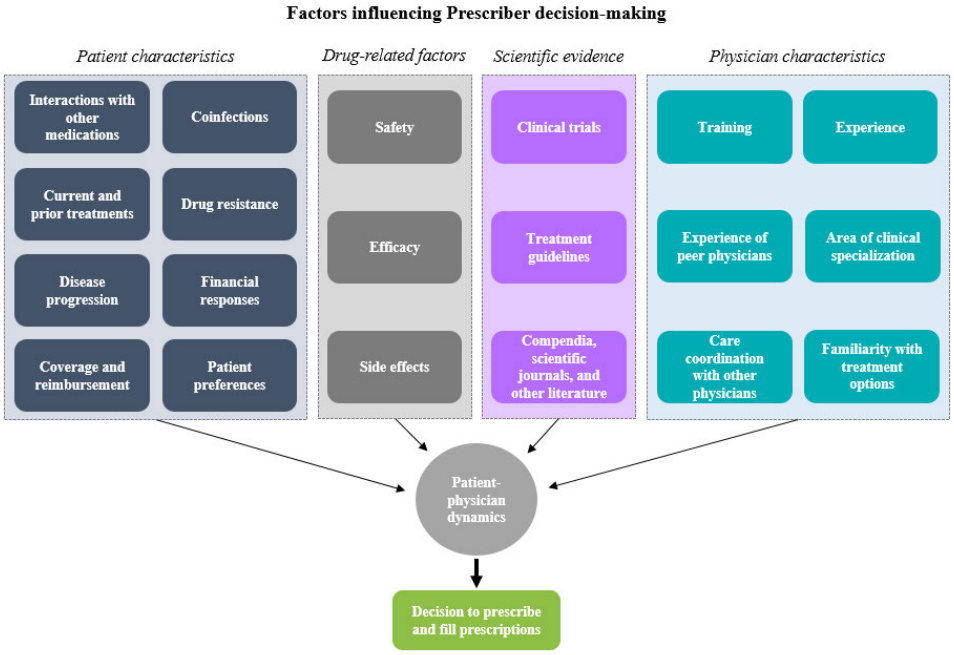
could prescribe Viread® or Vemlidy® based on a number of different factors and based on information from one or more of these sources, regardless of whether they received an honoraria payment from Gilead.

108. In this section, I describe these factors in detail. Additionally, I examine whether HBV OLP-related payments appear to have had any influence on prescribing behavior and explore differences between OLP participants and non-participants.

A. Many factors influence an HCP's decision to prescribe a particular drug

109. Treatment for HBV can be complex and can depend on clinical, patient, and physician considerations. Treatment decisions are typically made by specialists with years of training, who consider many factors alongside one another to determine the best treatment for patients. As shown in Exhibit 12, these include drug-related factors (e.g., efficacy, safety, side effects) and patient characteristics (e.g., comorbidities, co-infection of HIV and HBV, drug resistance, and history of medication adherence). Physician characteristics (e.g., professional experience, medical training, knowledge of scientific literature, medical guidelines, and treatment algorithms) and scientific evidence also contribute to the choice of a particular drug.

Excerpt of Exhibit 12



110. Published studies, treatment guidelines, and clinical trials are among the main resources physicians rely on to learn about new treatments or new uses for medications.[228] According to both the HBV treatment guidelines published by American Association for the Study of Liver Disease and HBV treatment algorithm developed by a panel of United States hepatologists, TDF (the active ingredient in Viread®), TAF (the active ingredient in Vemlidy®), and entecavir (the active ingredient in Baraclude) are preferred first-line antiviral treatment for chronic HBV in the US, with superior efficacy, tolerability, and high barriers to viral

[228] Bobbio, Marco, et al., "Completeness of reporting trial results: effect on physicians' willingness to prescribe," *The Lancet,* May 1994, Vol. 343(8907), pp. 1209-1211; *See also*, Stafford, Randall S., et al., "Impact of Clinical Trial Results on National Trends in α-Blocker Prescribing, 1996-2002," *Journal of the American Medical Association,* January 2004, Vol. 291(1), pp. 54-62; Kim, Nancy, et al., "The Impact of Clinical Trials on the Use of Hormone Replacement Therapy: A Population-Based Study," *Journal of General Internal Medicine,* 2005, Vol. 20, pp. 1026-1031.

resistance.[229] The goal of the antiviral treatment is to significantly suppress or eliminate HBV replication and thus prevent progression of liver disease to cirrhosis, liver failure, or hepatocellular carcinoma. Lamivudine, adefovir, and telbivudine are also approved antiviral treatments for chronic HBV in the United States. However, they are no longer the first-line choices due to inferior efficacy profiles and higher resistance rates.[230]

111. Many scientific studies have found that TDF has a superior or equivalent antiviral efficacy and resistance profile compared to other antiviral treatments for different subgroups of HBV patients. Two clinical trials have demonstrated that, for both short- and long-term, TDF leads to superior outcomes as compared to adefovir for both patients with active HBV replication and high infectivity, and patients with minimal or no HBV replication.[231] Comparing to entecavir, studies have found that TDF is more effective for certain groups of HBV patients.[232] TDF is also considered a "rescuer" therapy for patients with lamivudine resistance, as TDF is

---

[229] Terrault, Norah, et al., "Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance," *Hepatology*, 2018, Vol. 67(4), pp.1560-1599; Martin, Paul, et al., "A Treatment Algorithm for the Management of Chronic Hepatitis B Virus Infection in the United States: 2015 Update," *Clinical Gastroenterology and Hepatology*, 2015, Vol. 13, pp. 2071-2087; Keeffe, Emmet B, et al., "A Treatment Algorithm for the Management of Chronic Hepatitis B Virus Infection in the United States: 2008 Update," *Clinical Gastroenterology and Hepatology*, 2008, Vol. 6, pp. 1315 - 1341.

[230] Lamivudine was removed as a first-line treatment due to a high rate of resistance and inferior efficacy compared to TDF. TDF also replaced telbivudine and adefovir when clinical studies demonstrated that it had superior efficacy and resistance profiles. Finally, telbivudine is no longer considered a first-line treatment even though it has superior efficacy than lamivudine and adefovir because it has an intermediate rate of resistance (Keeffe, Emmet B., et al., *supra* note 229).

[231] Marcellin, Patrick, et al., "Tenofovir Disoproxil Fumarate versus Adefovir Dipivoxil for Chronic Hepatitis B," *New England Journal of Medicine*, 2008, Vol. 359(23), pp. 2442-2455; Marcellin, Patrick, et al., "Regression of cirrhosis during treatment with tenofovir disoproxil fumarate for chronic hepatitis B: a 5-year open-label follow-up study," *Lancet*, 2013, Vol. 381(9865), pp. 468 - 475.

[232] Cho, Eun Ju, et al., "Comparison of the Efficacy of Entecavir and Tenofovir in Nucleos(T)ide Analogue-Experienced Chronic Hepatitis B patients," *Plos One*, 2015, Vol. 10(6), pp. 1-10; Park, Ji Won, et al., *supra* note 31; Yim, Hyung Joon, I.H. Kim, S.J. Suh, et al., "Switching to Tenofovir vs Continuing Entecavir for Hepatitis B Virus with Partial Virologic Response to Entecavir: A Randomized Controlled Trial," Journal of Viral Hepatitis, 2018, Vol. 25(11), pp. 1321-1330.

proven to be effective in virus suppression without increased risk of TDF resistance.[233] Furthermore, TDF is the preferred treatment option for pregnant women with chronic HBV, demonstrating significant reduction in mother-to-child transmission of HBV.[234] Finally, as mentioned in Section III.B, TDF (Viread®) was originally approved for use in patients with HIV. For patients with coinfection of HIV and HBV, both the US Department of Health and Human Services and Antiviral Society-US panel guidelines suggest treatment with TDF plus either emtricitabine or lamivudine.[235]

112. TAF (Vemlidy®) has a similar efficacy profile to TDF (Viread®), but requires a lower dose and is thus associated with fewer potential side effects.[236] Two clinical studies found that TAF achieved similar outcomes as TDF, but with less decline in renal function and bone

---

233 Van Boemmel, Florian, et al., "First Multicenter Evaluation of the Efficacy of Tenofovir in Nucleo(t)ide Analog Experienced Patients with HBV Monoinfection," *Hepatology*, 2007, Vol. 46(4), pp. 270A-271A; Van Bommel, Florian, et al., "Tenofovir for Patients with Lamivudine-Resistant Hepatitis B Virus (HBV) Infection and High HBV DNA Level During Adefovir Therapy," *Hepatology*, 2006, Vol. 44(2), pp. 318-325.

234 Currently, TDF, lamivudine, and telbivudine are the only antiviral treatments with demonstrated safety in pregnant patients with HBV, and only TDF and telbivudine are classified as not teratogenic. Terrault, Norah, et al., *supra* note 229; Martin, Paul, et al., *supra* note 229; Brown, Robert, et al., "Antiviral Therapy in Chronic Hepatitis B Viral Infection During Pregnancy: A Systematic Review and Meta-analysis," *Hepatology*, 2016, Vol. 63(1), pp. 319-333; Pan, Calvin Q., et al., "Tenofovir to Prevent Hepatitis B Transmission in Mothers with High Viral Load," *New England Journal of Medicine*, 2016, Vol 374(24), pp. 2324-2334; Chen, Huey-Ling, et al., "Efficacy of Maternal Tenofovir Disoproxil Fumarate in Interrupting Mother-to-Infant Transmission of Hepatitis B Virus," *Hepatology*, Vol. 62(2), 2015, pp. 375-386.

235 Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV, *Department of Health and Human Services*, 2019, available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf; Thompson, Melanie A., et al., "Antiretroviral treatment of adult HIV infection: 2012 Recommendations of the International Antiviral Society-USA panel," *JAMA*, 2012, Vol. 308(4), pp. 387-402.

236 Terrault, Norah, et al., *supra* note 229.

density in some patients.[237] Additionally, studies also found that TAF is preferable to entecavir for certain groups of HBV patients.[238] Finally, studies have shown that switching from TDF to TAF helps HBV and HIV/HBV-coinfected patients to recover from renal dysfunction while maintaining the antiviral effects.[239]

113. Besides clinical studies, physicians' preferences about which medications to prescribe are formed by a variety of individualized characteristics and experiences, including their own past prescribing experiences, their peers' prescribing experiences, their clinical training (e.g., the medications that were typically prescribed during the physician's residency program), their familiarity with a medication, and its side effects. In my practice, I routinely prescribe medications to patients facing a range of symptoms and conditions. Like many other physicians, in addition to drawing on my own experiences and the experiences of my peers, I obtain information from many sources, including physician references such as "UpToDate," published scientific evidences, clinical guidelines, and professional society recommendations. These disparate experiences and sources of information not only create variability in physician practices and prescribing habits but are key determinants of these practice patterns.

---

[237] Chan, Henry LY, et al., "Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of HBeAg-positive chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial," *Lancet Gastroenterology Hepatology*, 2016, Vol. 1(3), pp. 185-195; Buti, Maria, et al., "Tenofovir alafenamide versus tenofovir disoproxil fumarate for the treatment of patients with HBeAg-negative chronic hepatitis B virus infection: a randomised, double-blind, phase 3, non-inferiority trial," *Lancet Gastroenterology Hepatology*, 2016, Vol. 1(3), pp. 196-206; Arribas, Jose R., et al., "Brief Report: Randomized, Double-Blind Comparison of Tenofovir Alafenamide (TAF) vs Tenofovir Disoproxil Fumarate (TDF), Each Coformulated With Elvitegravir, Cobicistat, and Emtricitabine (E/C/F) for Initial HIV-1 Treatment: Week 144 Results," *Journal of Acquired Immune Deficiency Syndrome*, 2017, Vol. 75(2), pp. 211-218.

[238] Hagiwara, Satoru, et al., "Switching from entecavir to tenofovir alafenamid versus maintaining entecavir for chronic hepatitis B," *Journal of Medical Virology*, 2019, Vol. 91(10), pp. 1804-1810.

[239] Kaneko, Shun, et al., "Tenofovir Alafenamide for hepatitis B virus infection including switching therapy from tenofovir disoprixil fumarate," *Journal of Gastroenterology and Hepatology*, 2019, Vol. 34(11), pp. 2004-2010; Surial, Bernard, et al., "Brief Report: Switching From TDF to TAF in HIV/HBV-Coinfected Individuals With Renal Dysfunction—A Prospective Cohort Study," *Journal of Acquired Immune Deficiency Syndromes*, 2020, Vol. 85(2), pp. 227-232.

114. As a physician gains more positive experiences with a therapy, he/she becomes more likely to prescribe it to other similarly situated patients. Conversely, negative experiences decrease the likelihood that a physician will prescribe that therapy to other similarly situated patients. Over time, these positive and negative experiences enable physicians to better identify patients for whom Viread® or Vemlidy® will provide an appropriate and effective treatment option. Furthermore, patients with positive treatment experiences are likely to continue using Viread®/Vemlidy® over an extended period of time, whereas patients who do not respond positively to Viread®/Vemlidy® are likely to cease treatment.

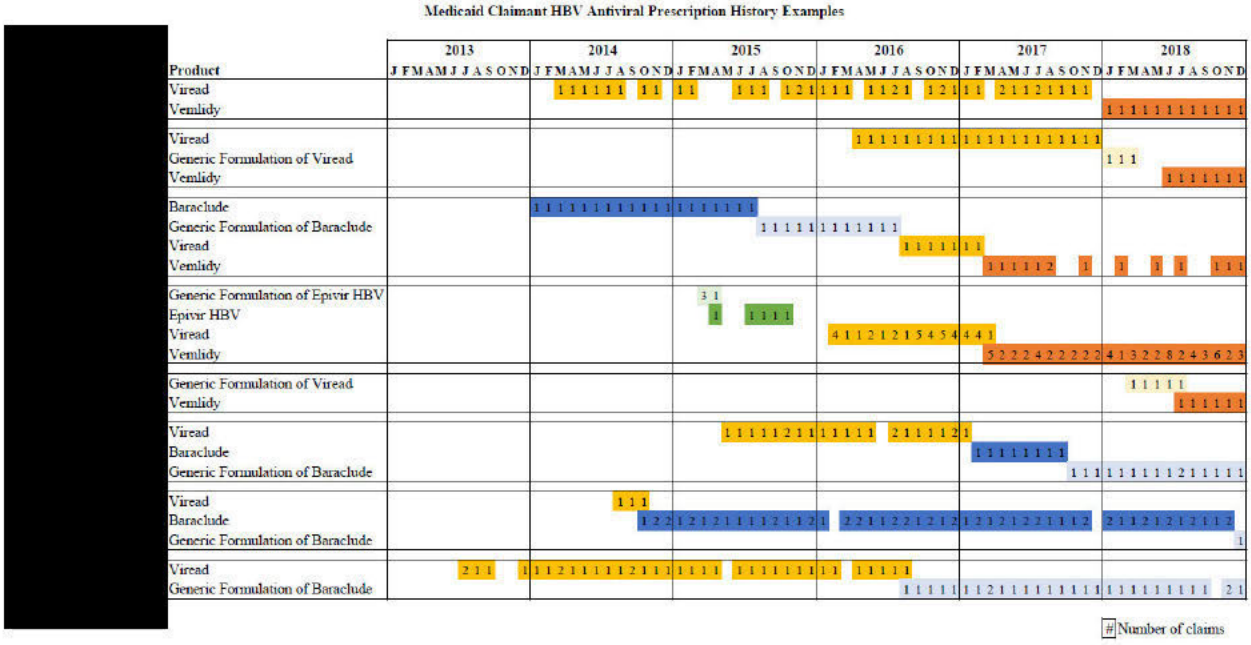
115. A physician's preferences may also be influenced by the experiences of their colleagues and peers. For example, physicians may discuss their positive or negative experiences with a specific drug with colleagues in their organization. In fact, various studies demonstrate the important role of information spillovers (i.e., where one person's information influences another person's adoption of new technologies) in the health care sector. For example, a 2018 study found that the presence of physician investigators who lead clinical trials in an area eases information friction and generates spillover effects of prescribing new cancer drugs by other physicians in the nearby area.[240]

116. Physicians also need to consider patient specific factors in their prescribing decisions, including patient characteristics and previous treatment experience. As discussed above, the preferred treatment choices may be different if the patient has coinfection of HIV and HBV, if the patient is pregnant, or if the patient has developed resistance to lamivudine or telbivudine. Similarly, patients with HBV infection whose disease onset is at different ages may

[240] Agha, Leila, and David Molitor, "The local influence of pioneer investigators on technology adoption: evidence from new cancer drugs," *Review of Economics and Statistics,* Vol. 100(1), 2018, pp. 29-44.

also require different treatment choices.[241] All of these factors lead to varying treatment patterns across individual patients. For example, Exhibit 13 displays different treatment patterns observed in Medicaid patients who at some point were treated with Viread® or Vemlidy®, suggesting different initiations, failures, and switching of treatments depending on the aforementioned factors.

Excerpt of Exhibit 13[242]



117. Taking into account the numerous factors considered by physicians in making prescribing decisions, it is my opinion that Viread® and Vemlidy® prescriptions likely were written as a result of these many considerations and should not be, without specific evidence, attributed to honoraria payments.

---

241 Komatsu, Haruki, et al., "Pediatric hepatitis B treatment," *Annals of Translational Medicine,* February 2017, Vol. 5(3), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5326647 ("Nucleos(t)ide analogues (NAs), such as lamivudine, adefovir, entecavir and tenofovir, are also available for the treatment of children, although the approval age differs among them.").

242 Claimants included in this analysis were required to have at least one non-HBV related claim at least three months prior to the first observed HBV-related claim to ensure the beginning of HBV treatment was captured. The Medicaid data include the prescribing history of patients who were prescribed either Viread® or Vemlidy® at some point during 2013-2018. CMS Medicaid claims data.

B. There is no correlation between OLP payments and physician prescribing

118. As mentioned above, if a physician's prescribing is not impacted by allegedly improper payments, then it calls into question whether those payments were truly improper. One way to test whether this impact occurred is to determine if there is a relationship between changes in payments and changes in Viread®/ Vemlidy® prescriptions from year to year for individual physicians. From an economic perspective, if little or no relationship were found, it would call into question the premise of payments being used to "incentivize" prescribing.

119. Gilead's engagement with OLP physicians varied over time. However, speakers' and advisors' prescribing of Gilead products did not fluctuate as payments increased or decreased. [redacted].[243] Exhibit 14 displays Gilead's total OLP honoraria payments alongside recipients' Viread® and Vemlidy® prescriptions. While Gilead payments through the OLP fluctuate substantially over time, [redacted], total Gilead prescriptions remained relatively constant up through entry of the generic formulation of Viread®. As expected, once the generic formulation of Viread® becomes available, total Gilead prescriptions decline as many physicians switch their patients to the generic formulation of Viread®. Moreover, total prescriptions (the sum of Viread® and Vemlidy®) remains lower after entry of the generic formulation of Viread®, as compared to the prior period.

[243] IMS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

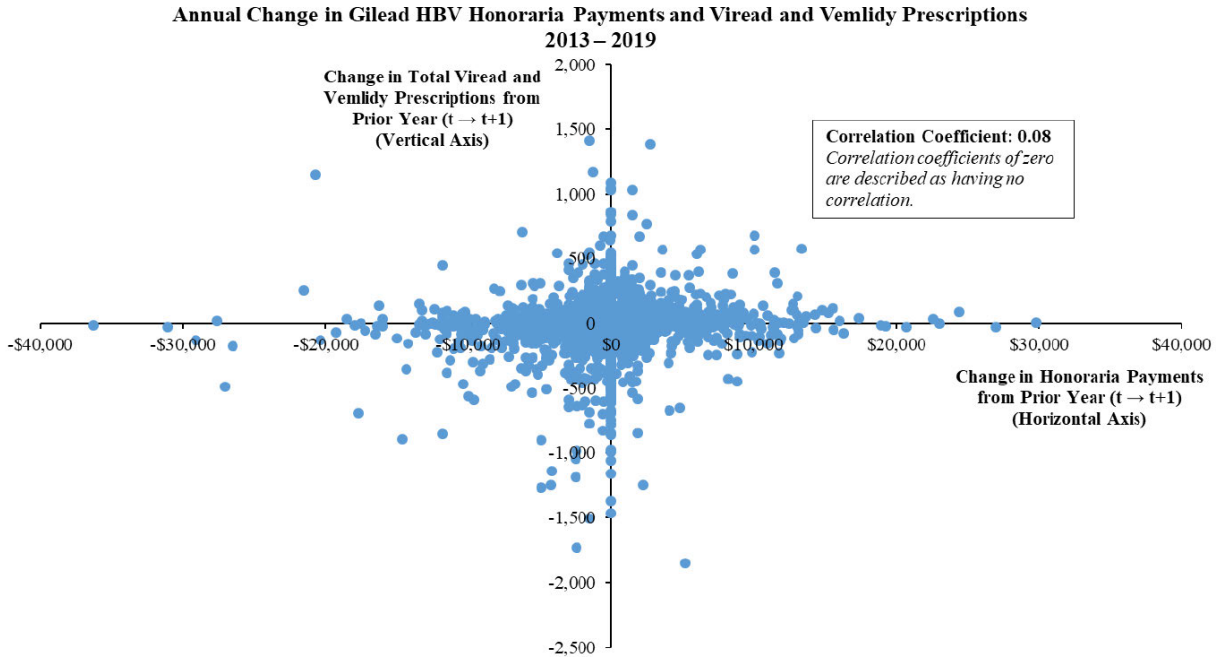
Excerpt of Exhibit 14[244]

120. The relationship (if any) between changes in Gilead OLP honoraria payments and changes in Gilead prescribing can also be measured statistically. Exhibit 15 assesses the relationship between annual changes in honoraria payments and prescribing of Gilead products from 2013 to 2019, at the physician-level. Dots in the upper left quadrant of the chart represent physicians who increased prescribing in years when payments decreased from the prior year. Dots in the lower right quadrant represent physicians who decreased prescribing when payments increased from the prior year. The overall correlation of 0.08 indicates no meaningful correlation

[244] HCPs who received any honoraria payments from AHM speaker programs, advisory board, or Non-AHM events (primarily speaker trainings) were included in the analysis. Speaker Program Spend Reports; Advisory Board Spend Reports; IMS/IQVIA Prescription Data.

between changes in payments and changes in prescribing at the physician-level.[245] The highly variable relationship between changes in payments and changes in prescribing suggests these physicians did not adjust prescribing in response to payments.

Excerpt of Exhibit 15[246]



121. The lack of a clear relationship between payments and prescribing can also be observed through the prescribing and payment patterns of individual physicians in the OLP. For example, Exhibit 16 shows that [redacted], when the

[245] *See, e.g.,* Taylor, Richard, EdD, RDCS, "Interpretation of the Correlation Coefficient: A Basic Review," *Journal of Diagnostic Medical Sonography*, January/February 1990, Vol. 6, pp. 35-39, at p. 37, available at https://journals.sagepub.com/doi/pdf/10.1177/875647939000600106, ("It is important to understand that it is possible to obtain a nonzero [correlation coefficient] even when no correlation actually exists… [C]orrelation coefficients (in absolute value) which are ≤ 0.35 are generally considered to represent low or weak correlations, 0.36 to 0.67 modest or moderate correlations, and 0.68 to 1.0 strong or high correlations with *r* coefficients ≥ 0.90 very high correlations."). *See also* Heumann, Christian et al., "Introduction to Statistics and Data Analysis," *Springer*, 2016, p. 83 ("If [correlation is close to zero], then it indicates that the variables are independent or the relationship is not linear.").

[246] This analysis excludes years where both the change in total honoraria and total prescriptions from the prior year are zero. Honoraria payments include payments from speaker events and advisory board events. IMS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

generic formulation of Viread® entered the market. Furthermore, [redacted] As observed at the aggregate level, individuals' prescribing of Gilead products does not appear directly related to payments received from Gilead.

Excerpt of Exhibit 16[247]

[redacted]

122. The prescribing and payment history of [redacted], another physician in the OLP, demonstrates a pattern of decreased prescribing over time despite relatively consistent payments from Gilead (see Exhibit 17). In 2015, [redacted]

[247] Non-AHM payments include payments primarily for speaker trainings. IMS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

Even when Vemlidy® came to market in 2017, [redacted] prescribing of Gilead products demonstrates the lack of a direct relationship between payments and prescriptions.

Excerpt of Exhibit 17[248]

[redacted]

123. As a final example, per Exhibit 18, Gilead's payments to another physician in the OLP, [redacted], over several years appeared to have no effect on prescribing. [redacted]

[248] Non-AHM payments include payments primarily for speaker trainings. IMS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

[redacted]

demonstrating Gilead's reliance on a physician's qualifications for inclusion in the OLP rather than their prescribing habits.

Excerpt of Exhibit 18[249]

[redacted]

C. Individuals who received speaker program and advisory board payments show nearly identical prescribing patterns to those who never received payments

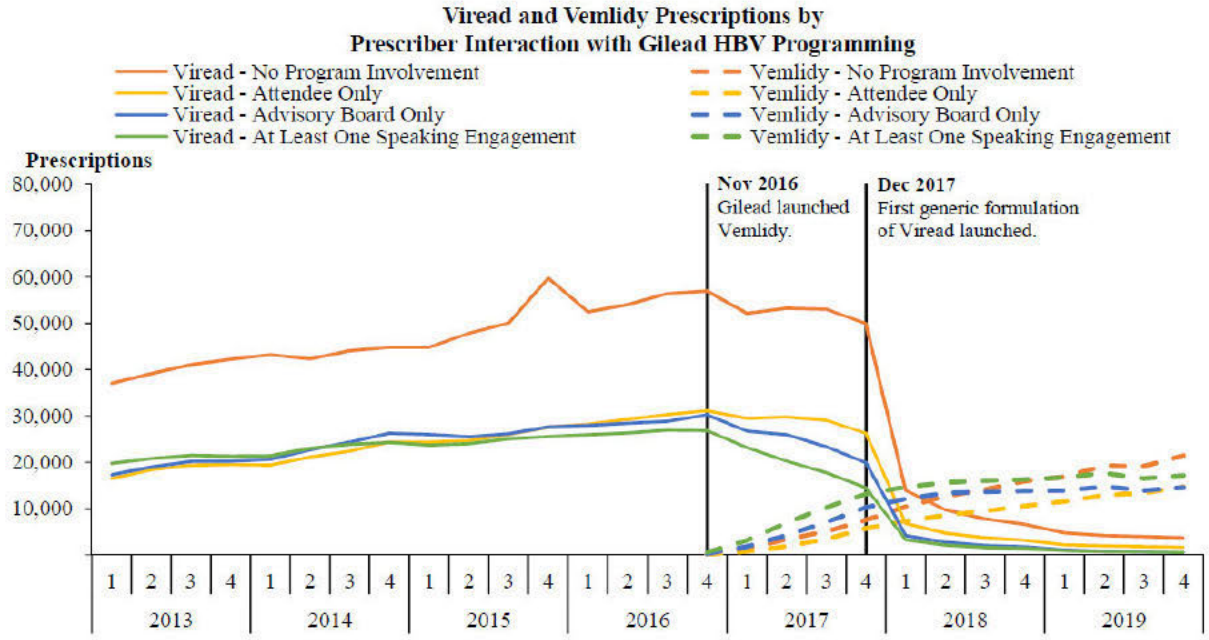
124. Another approach to assessing whether Gilead OLP payments functioned as kickbacks is to compare the prescribing behavior of those who did receive payments to those who did not. If Gilead's OLP speaker and advisory board payments were influencing recipient prescribing behavior, we would expect to see different patterns between physicians who received honoraria payments and those who did not.

[249] Non-AHM payments include payments for primarily for speaker trainings. IMS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

125. Exhibit 19 compares prescribing patterns of those who (1) never had any involvement with Gilead OLPs ("No Program Involvement" Group), (2) only ever attended a speaker program but never received an honoraria payment ("Attendee Only" Group), (3) attended advisory board programs but never received honoraria payments for a speaker program ("Advisory Board Only" Group), and (4) participated as a speaker in at least one Gilead speaker program event ("At Least One Speaking Engagement" Group).[250] All four groups exhibit fairly consistent patterns, with some notable differences, none of which necessarily indicates that Gilead OLP payments functioned as kickbacks.

[250] This category includes *anyone* who was a speaker and received an honoraria payment for a speaker program. Some individuals may have also received honoraria for advisory board programs or been to speaking events as attendees, while others may have only received a speaker honoraria payment and had no other involvement in Gilead OLPs.

Excerpt of Exhibit 19[251]



126. First, individuals in the "Advisory Board Only" and "At Least One Speaking Engagement" groups begin prescribing Vemlidy® more quickly once it entered the market compared to the "No Program Involvement" and "Attendee Only" groups. Given that speakers and advisors mostly specialize in HBV treatment, I would expect them to be more knowledgeable about the benefits of newly available treatments and transition patients to these new treatments once they become available. Indeed, by the end of 2019, the "No Program Involvement" group also started to prescribe Vemlidy® more readily (and surpassed the other

[251] Physicians are categorized based on all Gilead interactions for speaker programs and advisory boards over the 2013 – 2019 time period. The "No Program Involvement" group includes physicians who never attended or received honoraria related to Gilead HBV programming between 2013 - 2019. The "Attendee Only" group includes physicians who attended a Gilead HBV program but never received speaker program or advisory board honoraria. The "Advisory Board Only" group includes physicians who received an HBV advisory board payment but never received an HBV speaker payment. The "At Least One Speaking Engagement" group includes physicians who ever received speaker payments for AHM or non-AHM speaker events or speaker training. [redacted] MS/IQVIA Prescription Data; Speaker Program Spend Reports; Advisory Board Spend Reports.

groups partway through 2019), reflecting a learning process that moves more slowly for physicians who are not benefitting from the learnings associated with these types of programs.

127. Second, all four groups dramatically reduce their Viread® prescribing following generic entry. While the decline is slightly larger for the "No Program Involvement" and "Attendee Only" groups, these groups actually continue to prescribe more branded Viread® through the end of 2019 than the "At Least One Speaking Engagement" and "Advisory Board Only" groups, despite the automatic substitution that occurs once a generic becomes available.

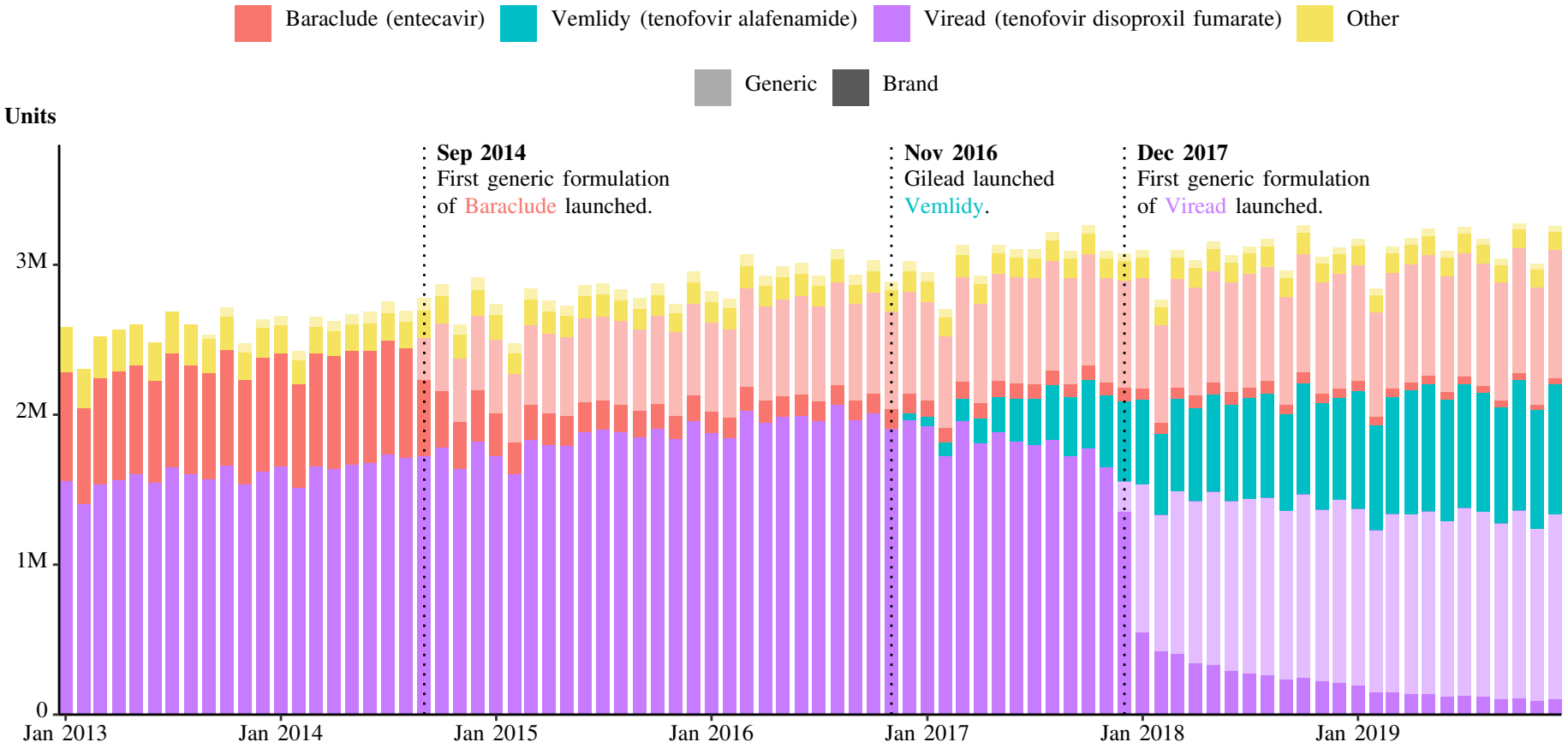
128. Consistent with my assessment of Gilead's OLPs and analyses comparing payment and prescribing changes, the comparison between OLP participants and non-participants indicates that there is no relationship between Gilead OLP payments and physician prescriptions. The lack of OLP payment impact on Viread® and Vemlidy® prescribing indicates that the alleged kickbacks seemingly had no effect on prescribing patterns for involved physicians, and supports that the government has not experienced any damages related to the Gilead OLP.[252]

Anupam B. Jena, M.D., Ph.D.

May 3, 2021

[252] I reserve the right to perform a damages calculation in response to Relators in the event that they demonstrate any Gilead HBV OLP payments appear to have improperly induced prescribing of Viread® and Vemlidy®.

Exhibit 1
HBV Oral Antiviral Treatment Unit Sales
2013 - 2019



Notes:
[1] The set of drugs included in this analysis is based on HBV treatment guidelines, both from public sources and from documents produced by Gilead.
[2] "Other" includes all branded and generic versions of Hepsera (adefovir dipivoxil), Tyzeka (telbivudine), and Epivir HBV (lamivudine HBV).

Sources:
[1] Symphony Health Data (accessed on March 18, 2021).
[2] "Approved Drugs for Adults," *Hepatitis B Foundation.*

Exhibit 2

Exhibit 3

Exhibit 4

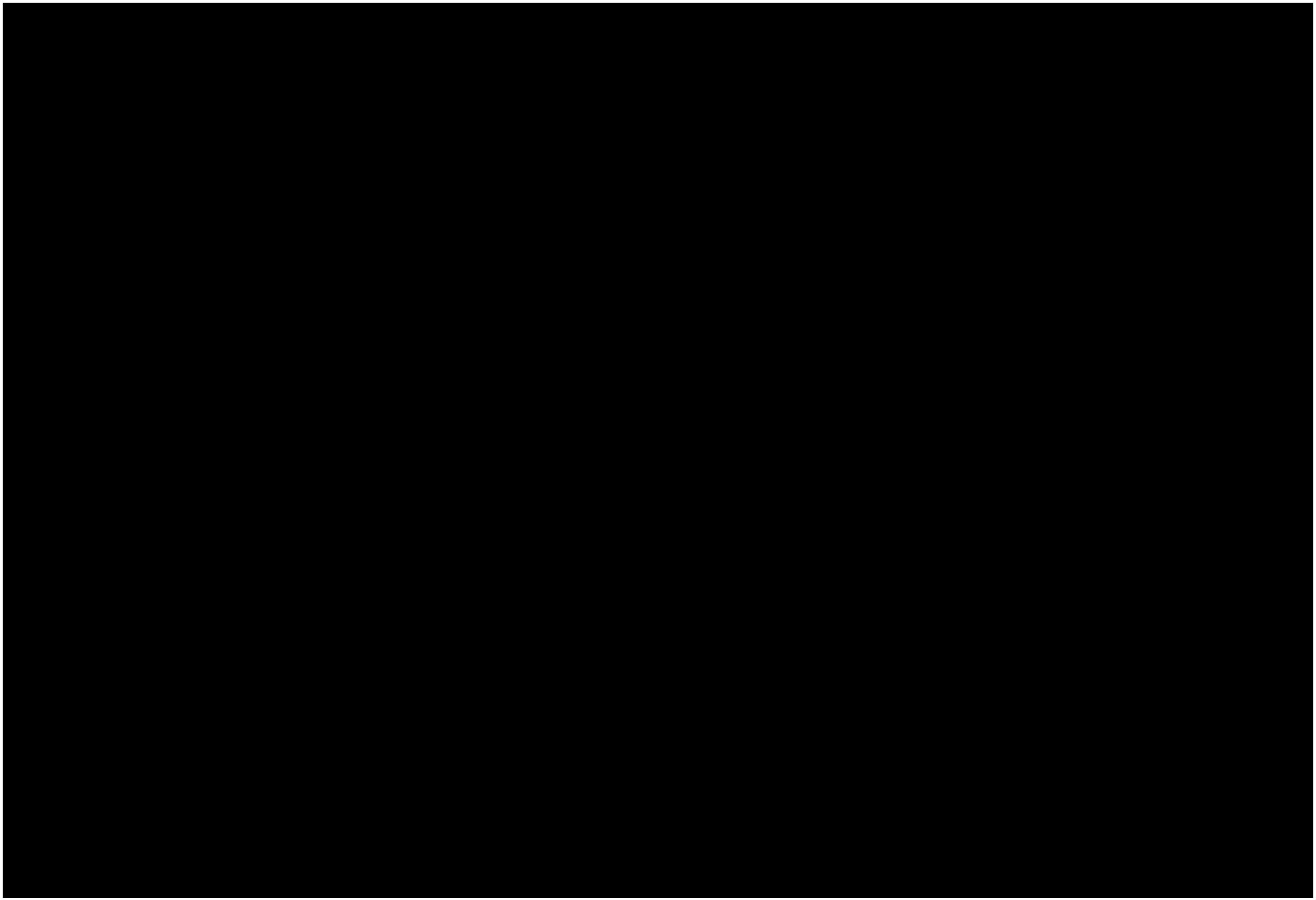


Exhibit 5

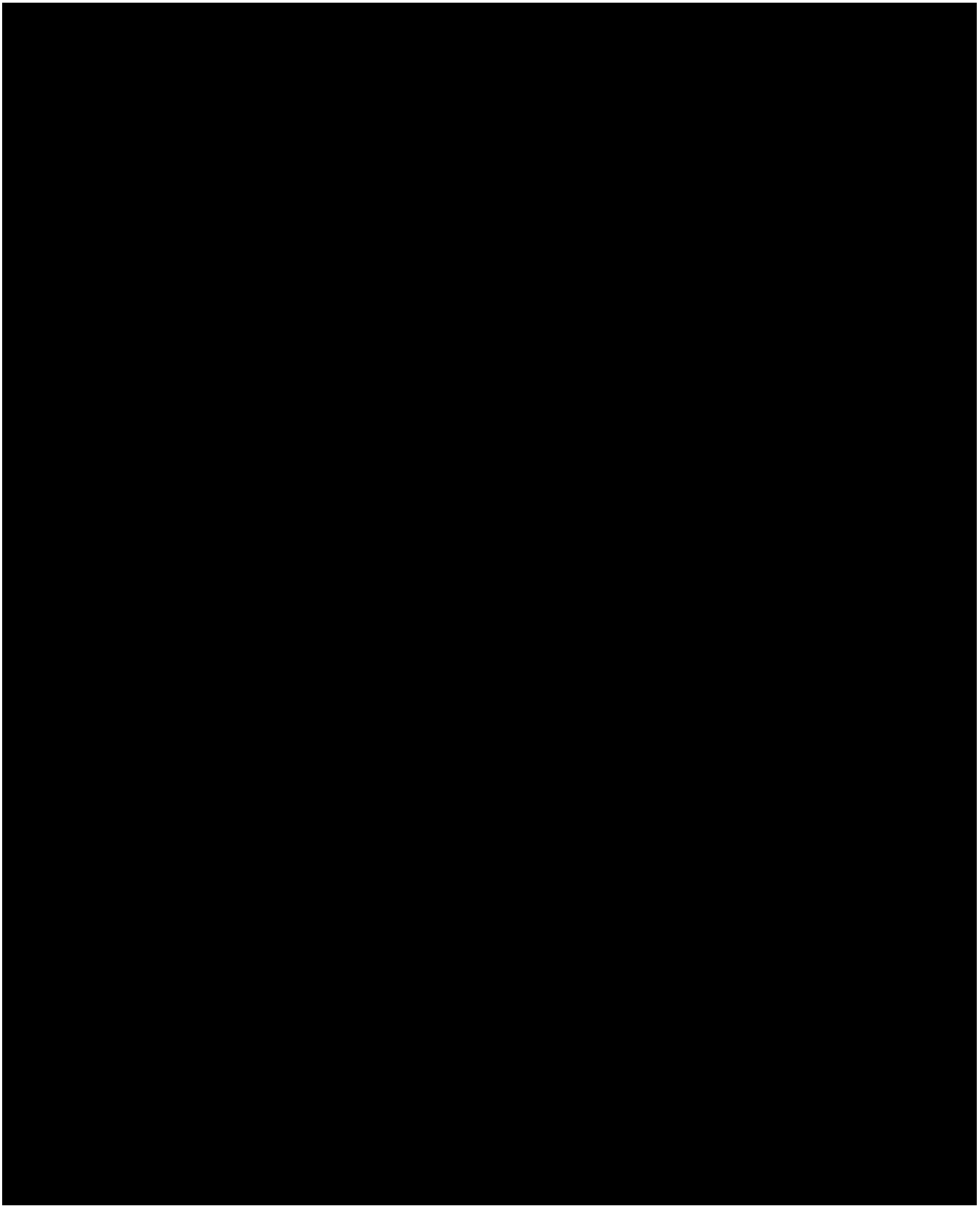


Exhibit 6

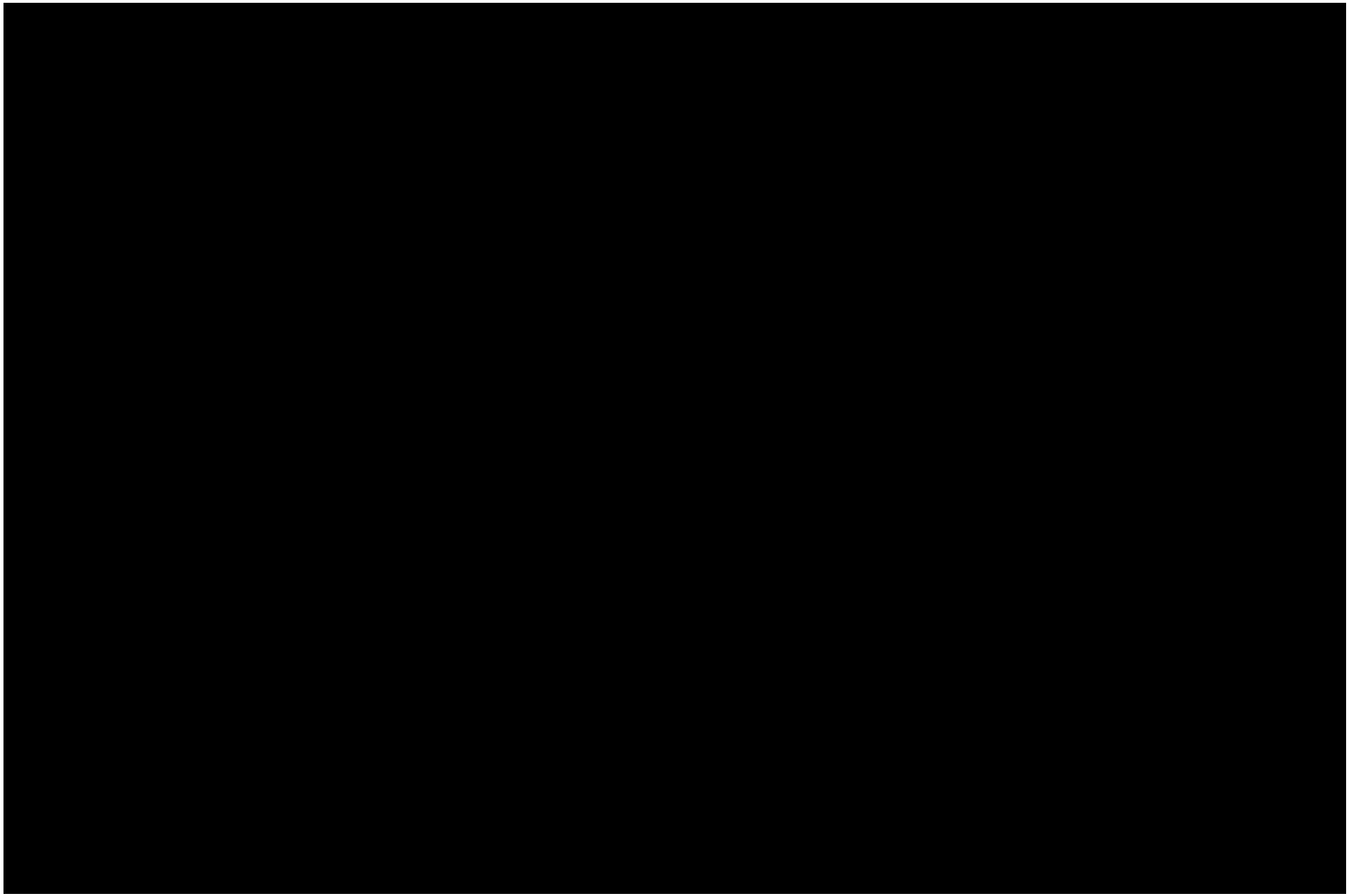


Exhibit 7

Exhibit 8

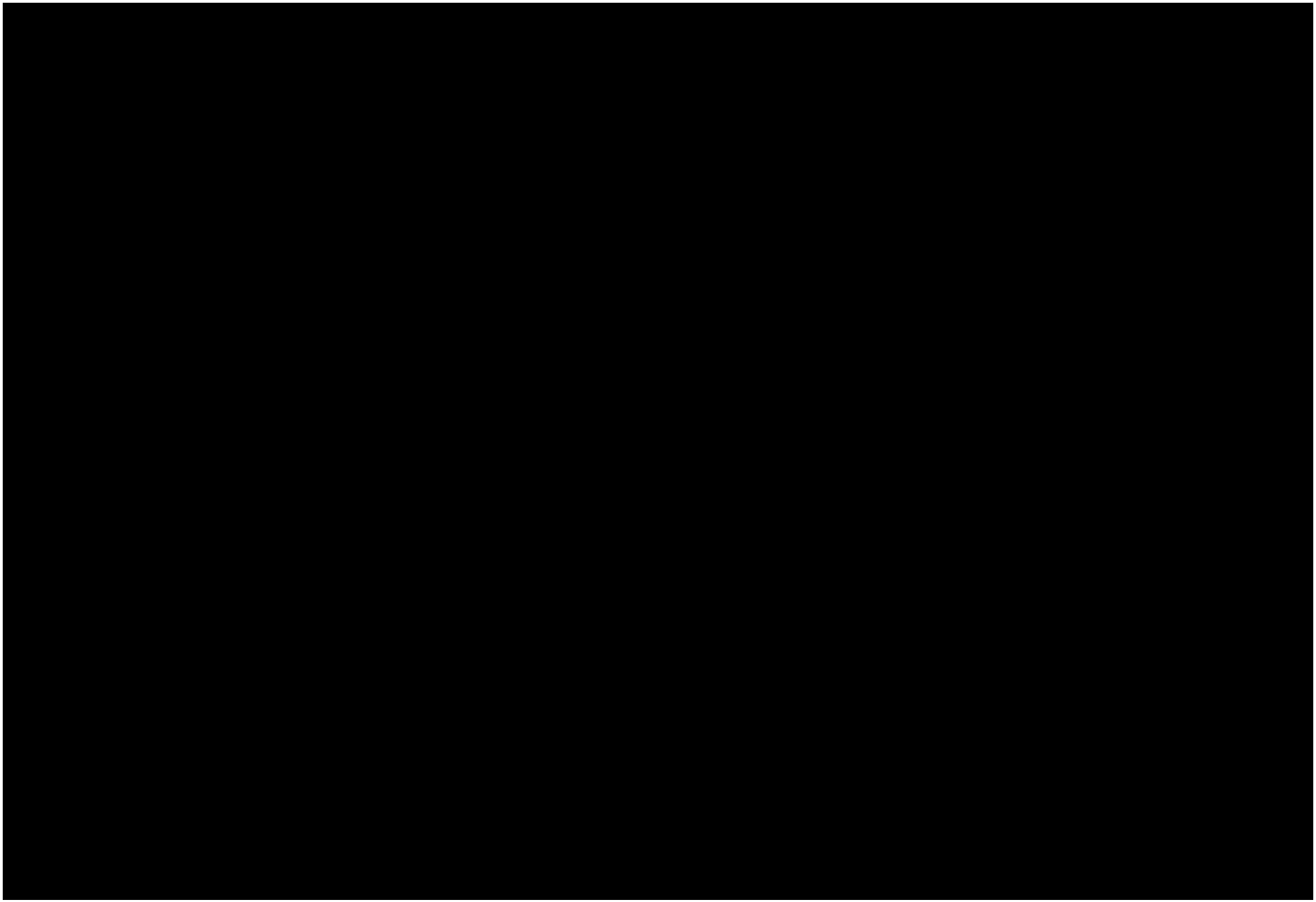


Exhibit 9

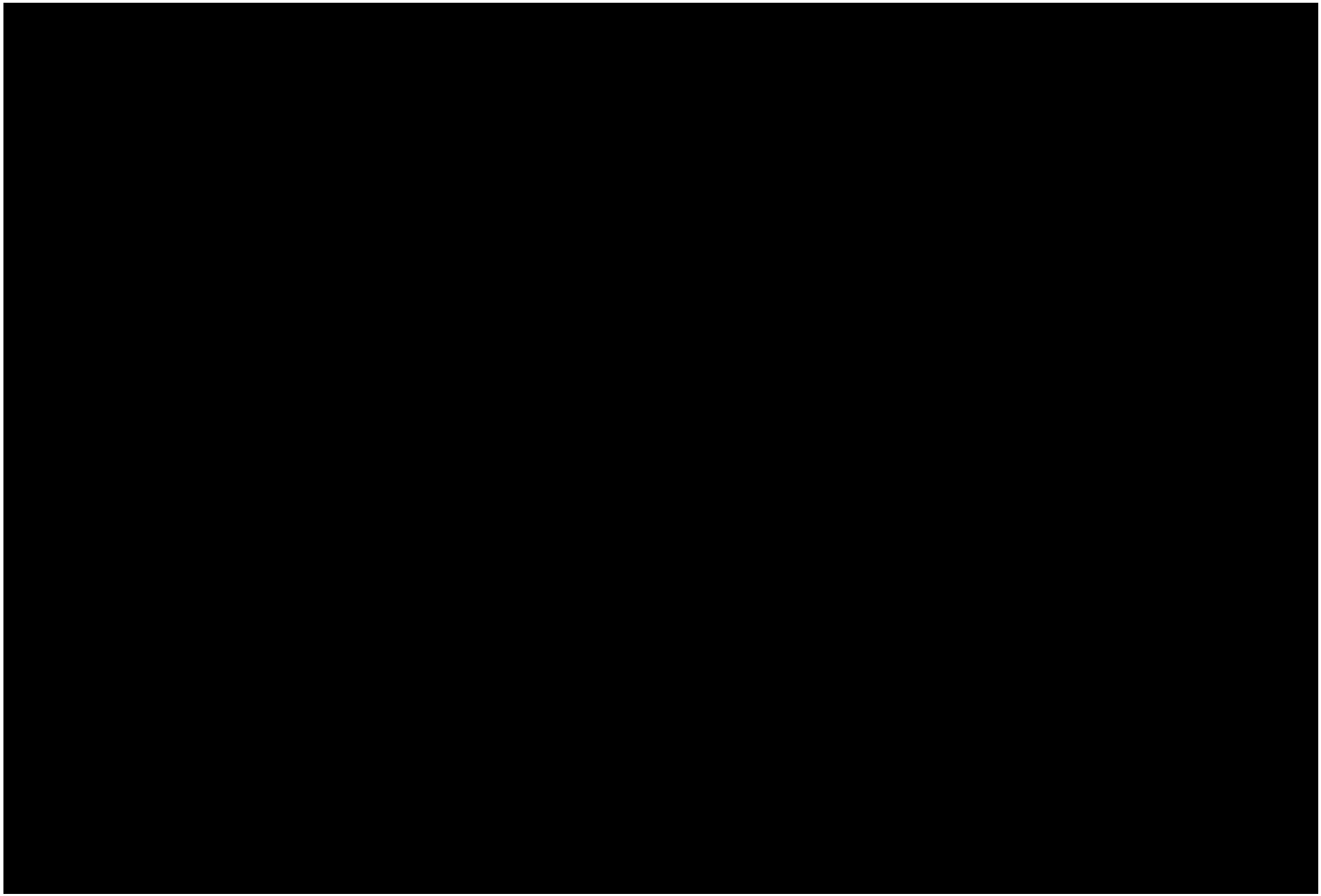


Exhibit 10

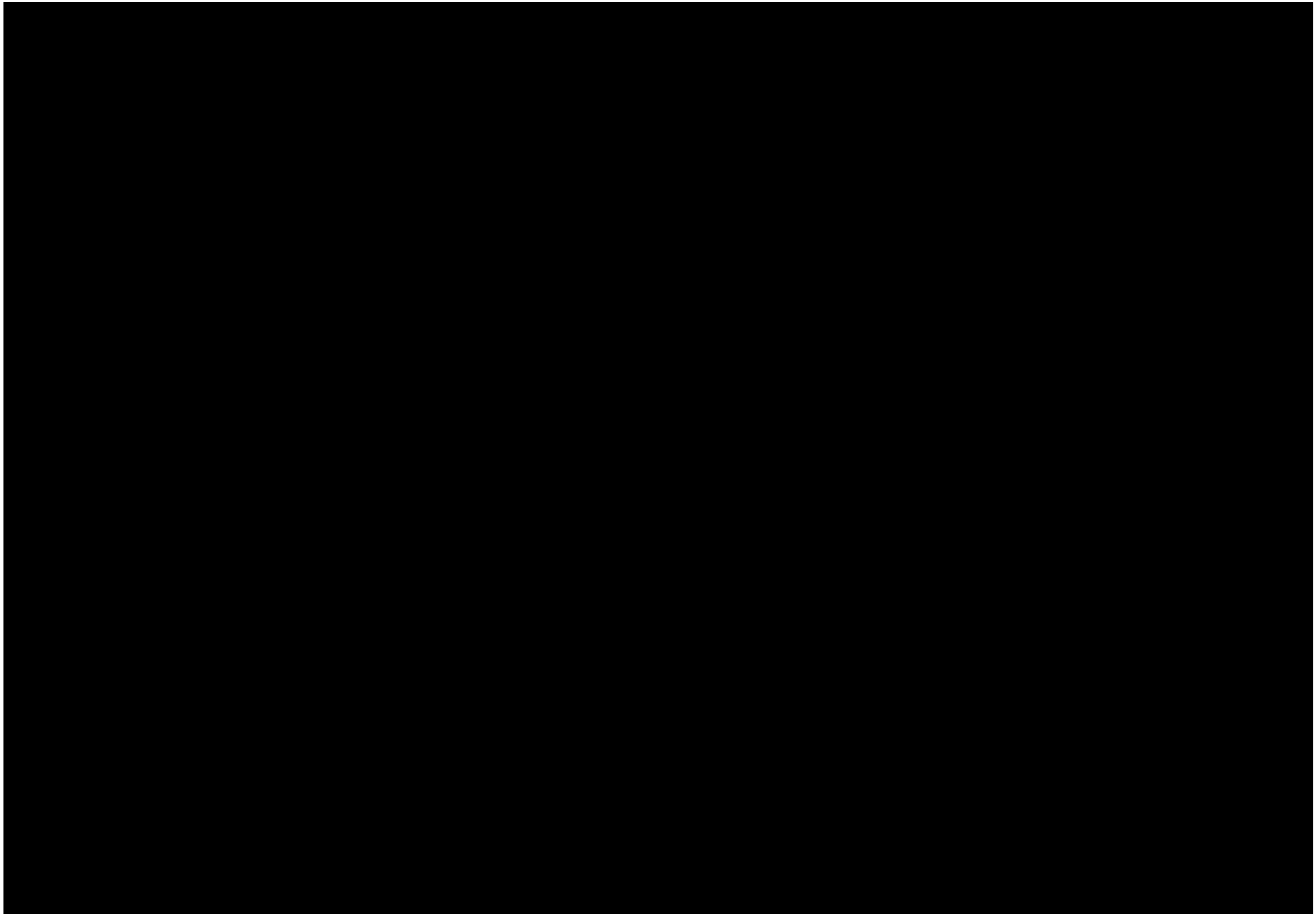


Exhibit 11

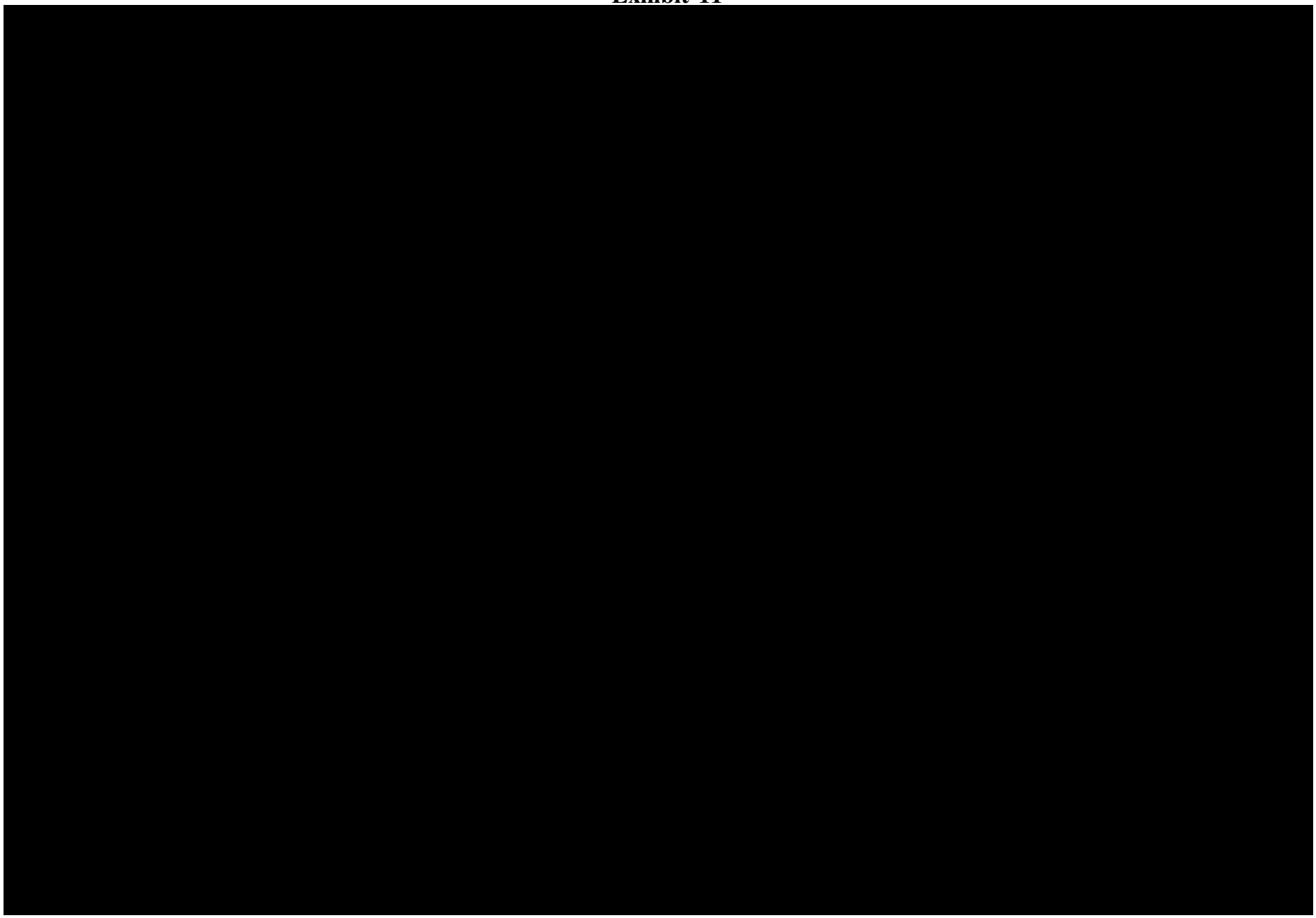


Exhibit 12
Factors influencing Prescriber decision-making

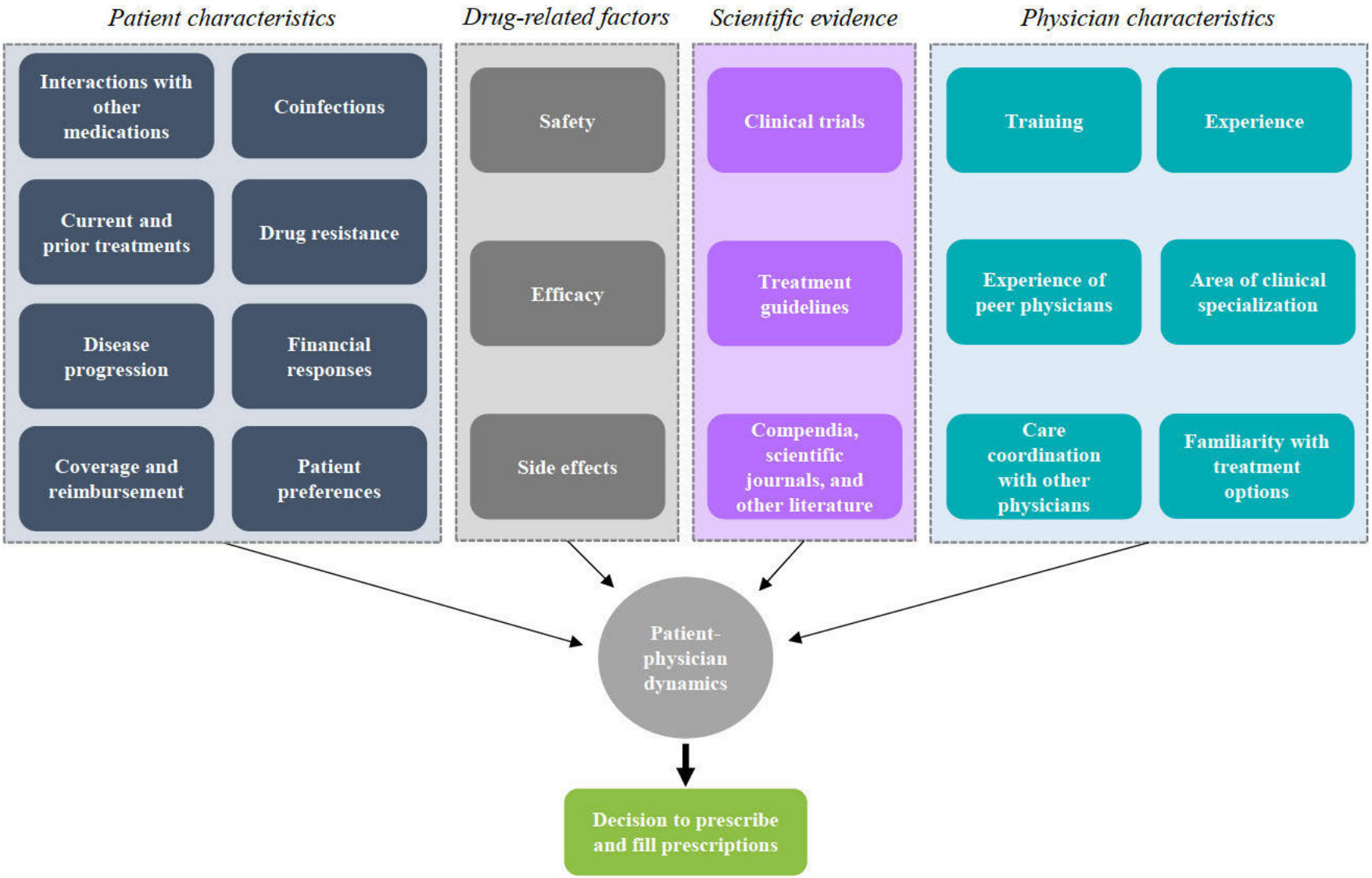
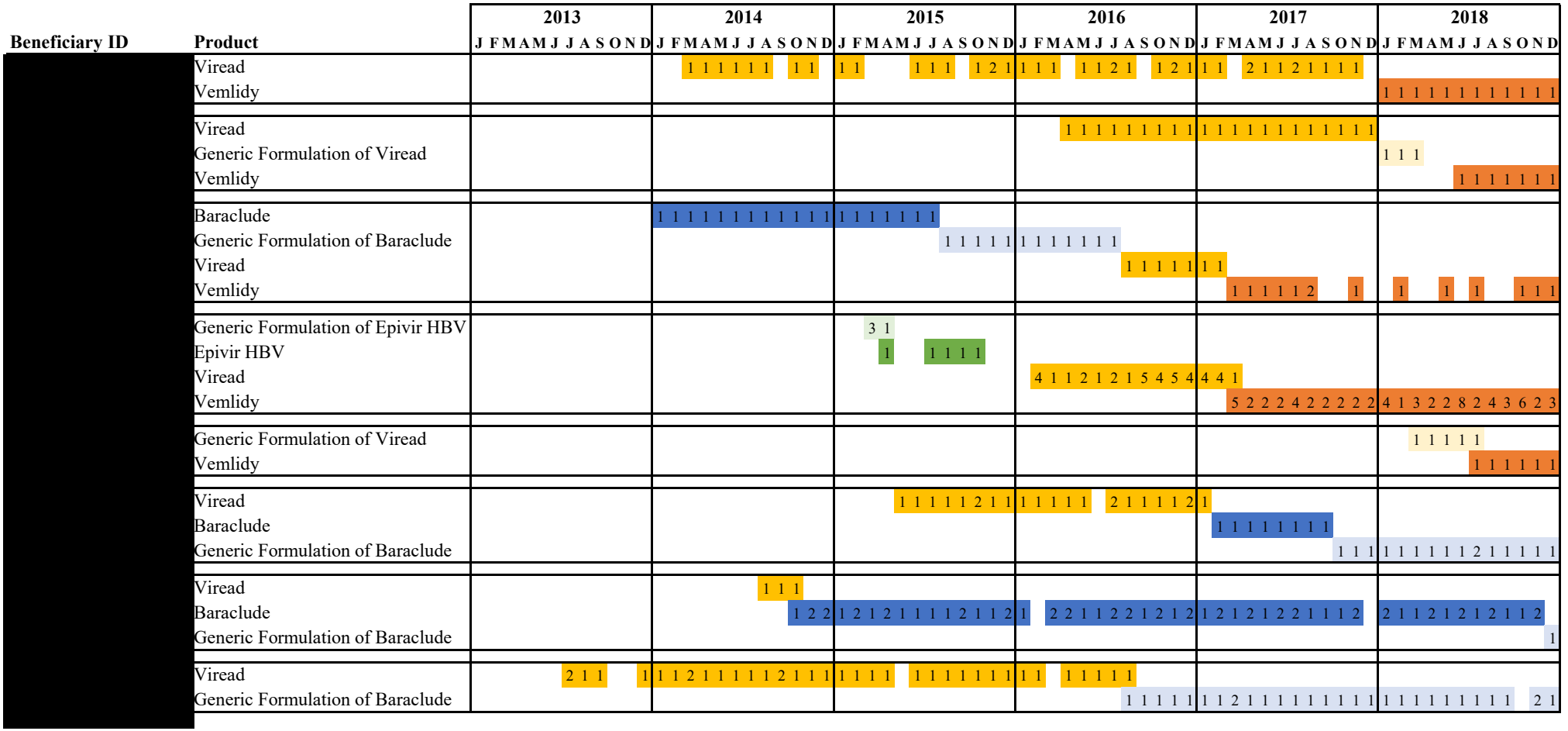


Exhibit 13
Medicaid Claimant HBV Antiviral Prescription History Examples



Number of claims

Notes:

[1] Claimants included in this analysis were required to have at least one non-HBV related claim at least three months prior to the first observed HBV-related claim to ensure the beginning of HBV treatment was captured.

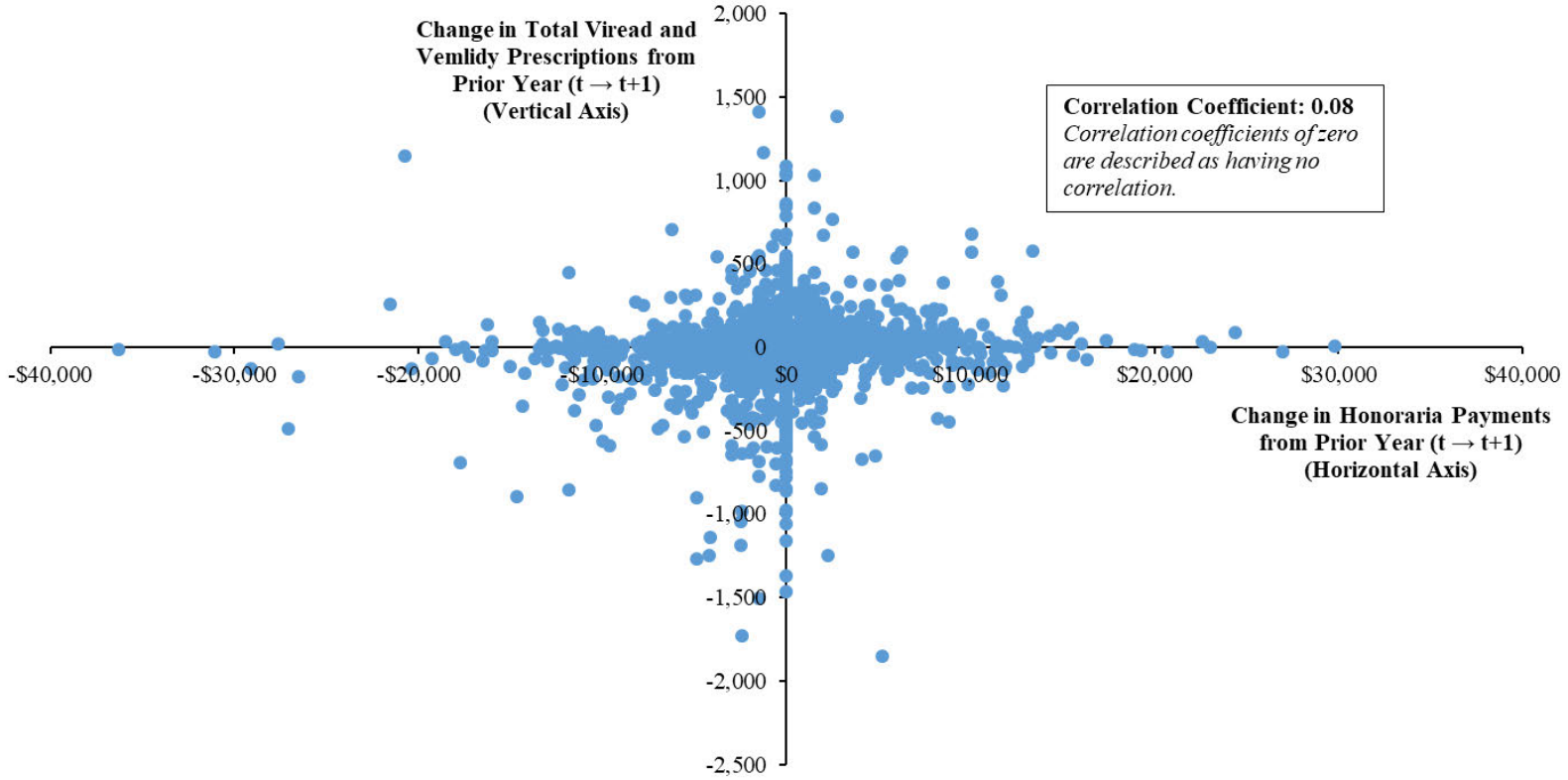
[2] The Medicaid data include the prescribing history of patients who were prescribed either Viread or Vemlidy at some point during 2013-2018.

Source:

[1] CMS Medicaid claims data.

Exhibit 14

Exhibit 15
Annual Change in Gilead HBV Honoraria Payments and Viread and Vemlidy Prescriptions
2013 – 2019



Notes:
[1] This analysis excludes years where both the change in total honoraria and total prescriptions from the prior year are zero.
[2] Honoraria payments include payments from speaker events and advisory board events.

Sources:
[1] IMS/IQVIA prescription data from January 2013 to December 2019 (Gilead_Purcell_00224639, 00311272, 00327018, 00340769).
[2] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[3] Advisory Board Spend Reports (Gileaad_Purcell_00134580, 00216563, 00311268, 00327017).

Exhibit 16

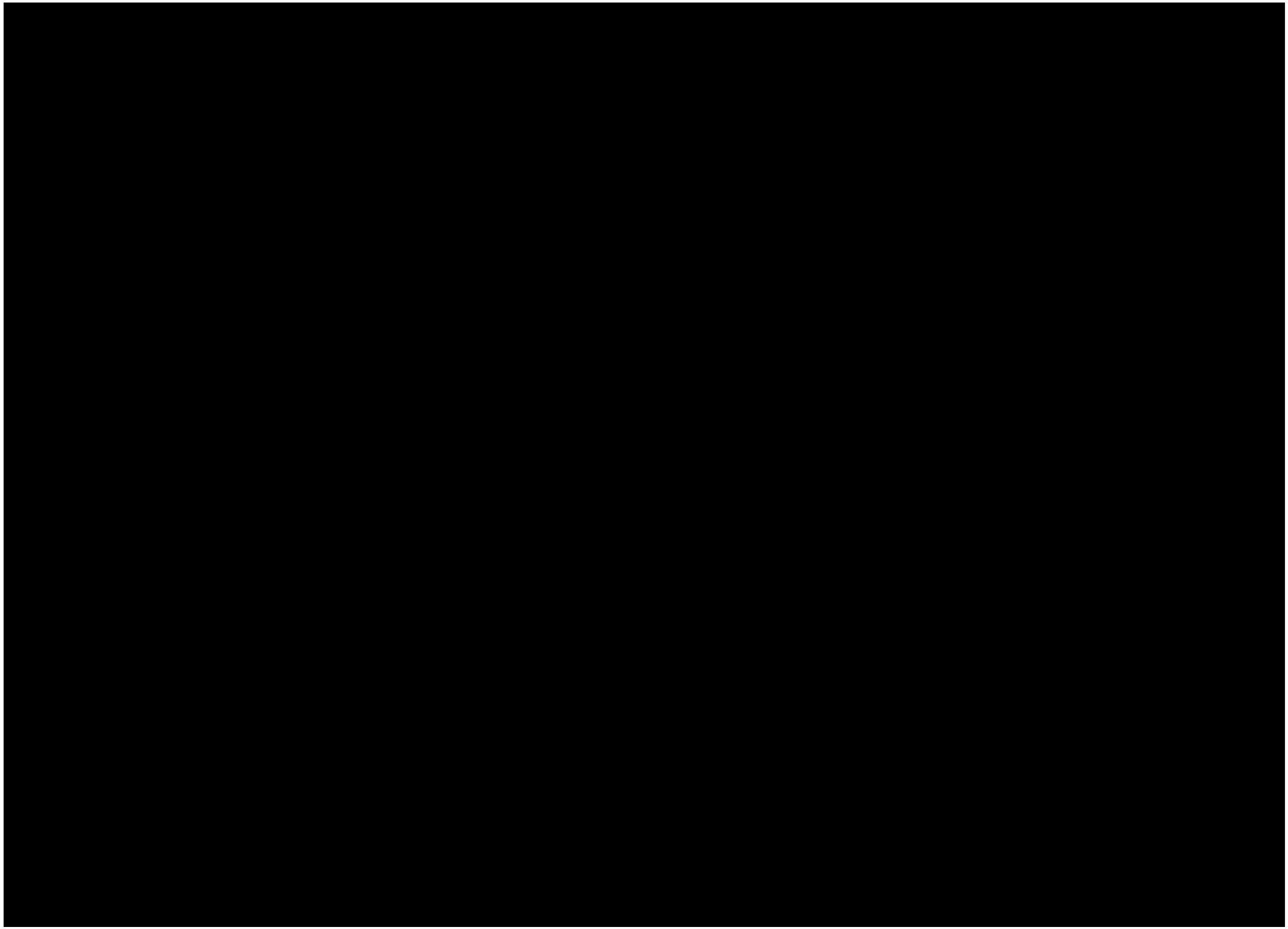


Exhibit 17

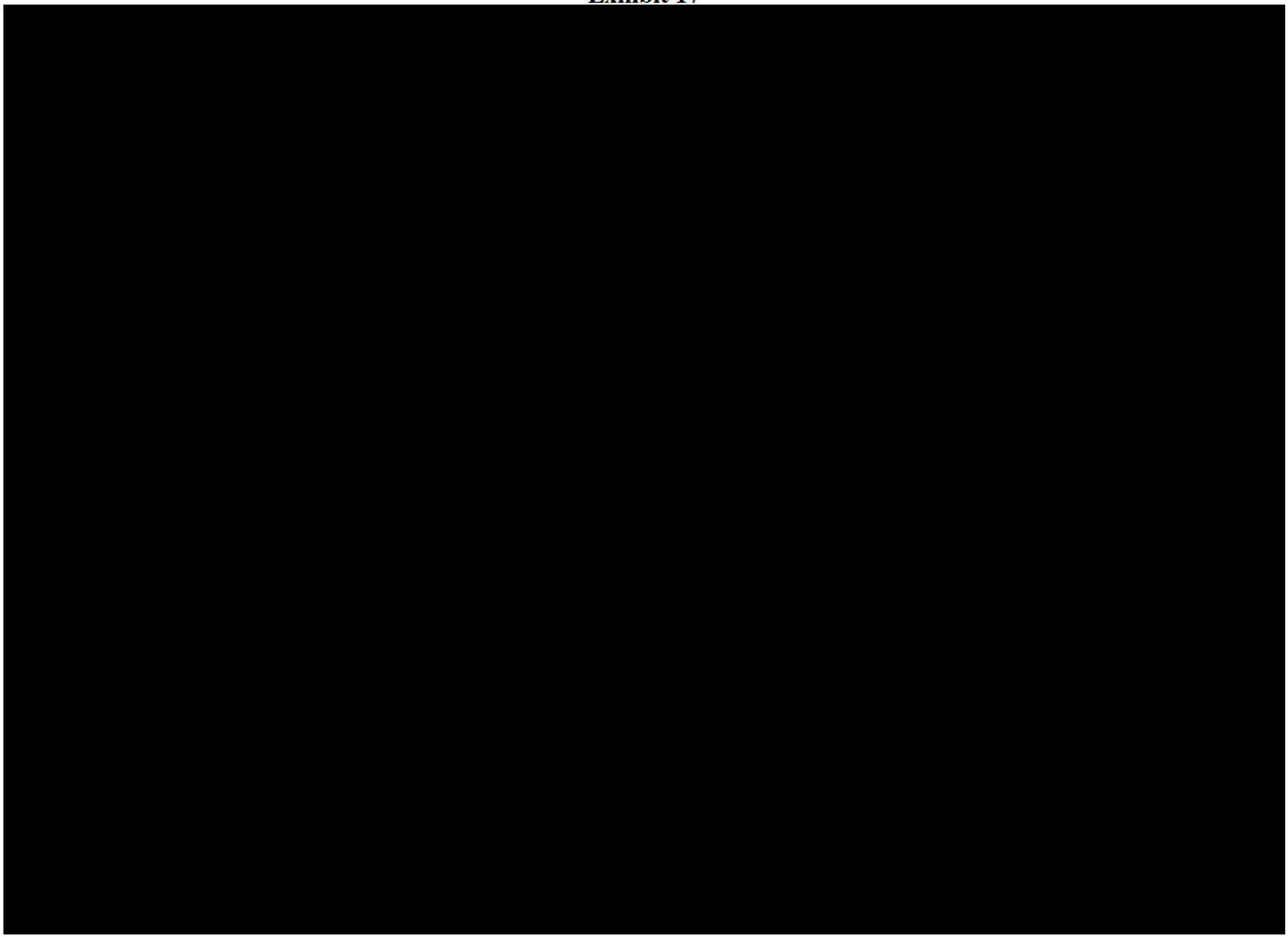


Exhibit 18

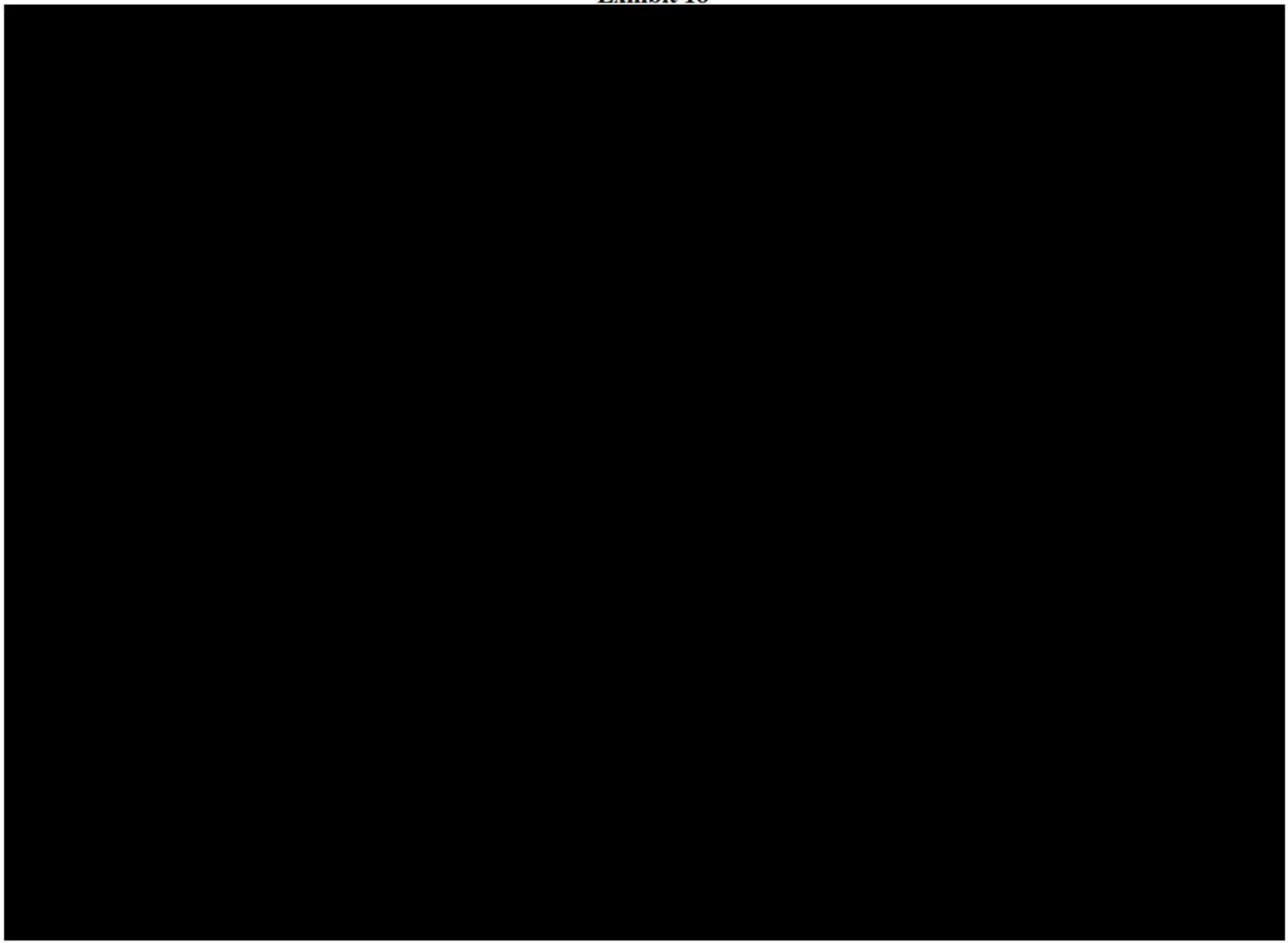
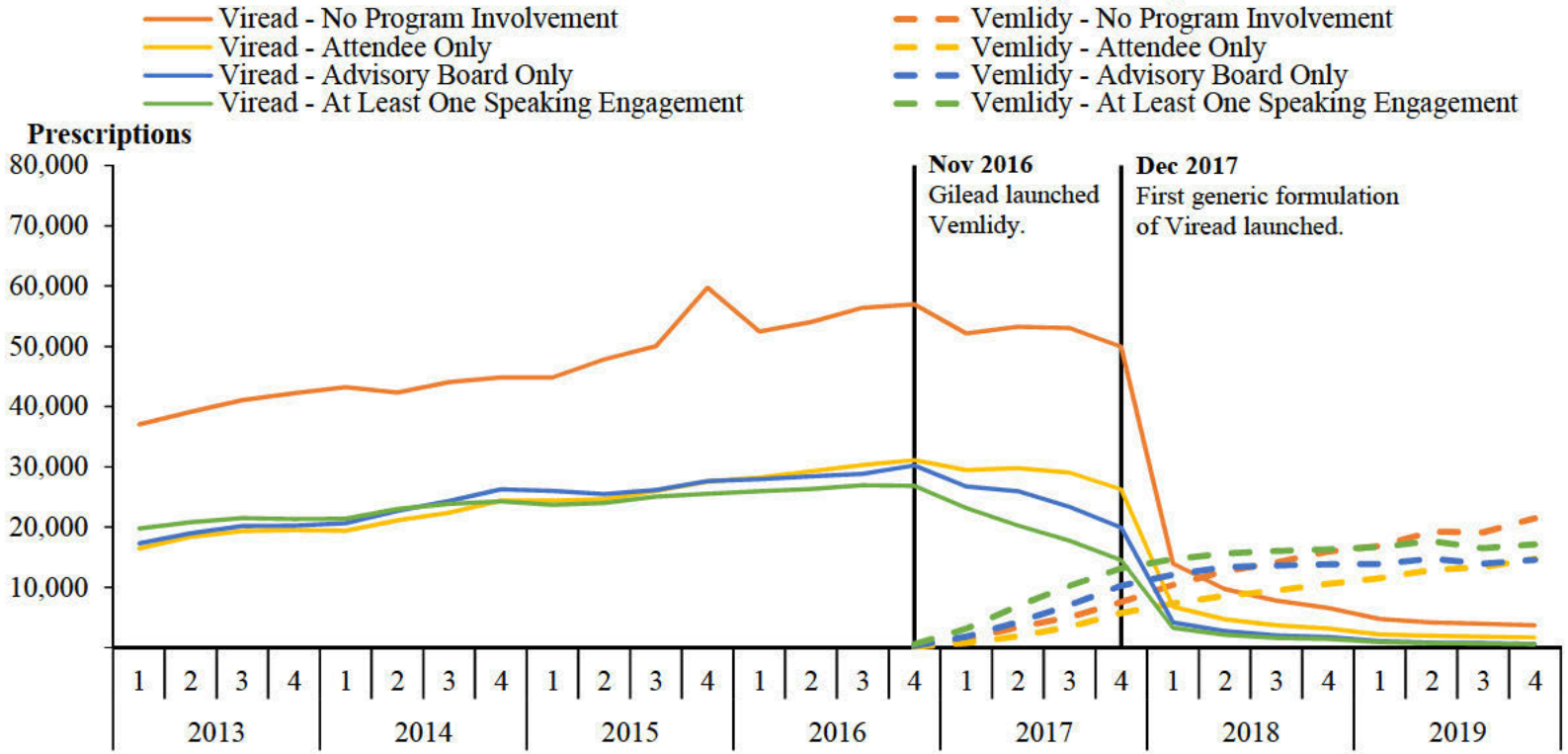


Exhibit 19
Viread and Vemlidy Prescriptions by
Prescriber Interaction with Gilead HBV Programming



Notes:
[1] Physicians are categorized based on all Gilead interactions for speaker programs and advisory boards over the 2013 – 2019 time period.
[2] The "No Program Involvement" group includes physicians who never attended or received honoraria related to Gilead HBV programming between 2013 - 2019. The "Attendee Only" group includes physicians who attended a Gilead HBV program but never received speaker program or advisory board honoraria. The "Advisory Board Only" group includes physicians who received an HBV advisory board payment but never received an HBV speaker payment. The "At Least One Speaking Engagement" group includes physicians who ever received speaker payments for AHM or non-AHM speaker events or speaker training.

[redacted]

Sources:
[1] IMS/IQVIA prescription data from January 2013 to December 2019 (Gilead_Purcell_00224639, 00311272, 00327018, 00340769).
[2] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[3] Advisory Board Spend Data (Gilead_Purcell_00134580, 00311268, 00327017, 00216563).

Exhibit B

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVNIA

UNITED STATES OF AMERICA, CALIFORNIA, ILLINOIS, NEW JERSEY, NEW YORK and TEXAS *ex rel.* CHRIS PURCELL and KIMBERLY GROOME Plaintiffs, v. GILEAD SCIENCES, INC. Defendant.	Case No. 2:17-cv-3523-MAK

EXPERT REBUTTAL REPORT OF DR. ANUPAM B. JENA, MD, PhD

May 26, 2021

TABLE OF CONTENTS

I. BACKGROUND AND ASSIGNMENT

1. I have been asked by Counsel for Gilead to review certain opinions put forth by Relators' experts and provide a response to those opinions. I previously submitted an affirmative Report in this matter on May 3, 2021 (hereafter "Initial Report"); my qualifications and case background are described in my Initial Report.[1]

2. First, I have been asked to evaluate the Expert Report of Dr. Genevieve Kanter, including her opinions on whether Gilead payments for speaker and advisory board programs influenced prescribing of Viread® and Vemlidy®, and whether physicians would be aware of this alleged influence.[2] Additionally, I have been asked to assess the analyses put forth by Dr. Hay in his expert report,[3] which both Dr. Hay and Dr. Kanter describe as examining the relationship between speaker and advisor payments and Viread®/Vemlidy® prescribing.

3. Second, I have been asked to evaluate the damages calculations put forth in the Hay Corrected Report and provide an alternative damages calculations, assuming certain of Relators' allegations are determined to be accurate.[4]

4. Third, I have been asked to evaluate the Expert Report of Vernon Biaett,[5] including whether his opinion that Gilead's speaker programs were held at inappropriate venues and that Gilead's $125 per person meal was "excessive."

---

1 Expert Report of Anupam B. Jena, May 3, 2021 (hereafter "Initial Report").

2 Expert Report of Professor Genevieve P. Kanter, May 3, 2021 (hereafter "Kanter Report").

3 Dr. Hay's May 3, 2021 report was untitled. In addition, I understand that Relators filed a "corrected" version of Dr. Hay's report that is similarly untitled, but that includes changes to account for certain errors in Dr. Hay's original report. This new report is dated May 9, 2021, and I refer to this report hereafter as the "Hay Corrected Report."

4 My review of Dr. Hay's analyses are ongoing and I reserve the right to provide additional critiques.

5 Expert Report of Vernon L. Biaett, May 3, 2021 (hereafter "Biaett Report").

5. This report and the opinions expressed herein are based on my analysis of the information and materials available to me as of the date of this report, as well as my training in medicine and health economics. To the extent I rely on my medical training and clinical experience to reach any opinions expressed in this report, I hold those opinions to a reasonable degree of medical certainty. Similarly, I hold my economic-related opinions to a reasonable degree of professional certainty in the field of economics. I reserve the right to amend or supplement this report in the event that new information relevant to my opinions is produced in this case. A list of the additional materials that I relied on, beyond those included in my Initial Report which I incorporate by reference, is included in **Appendix C - Rebuttal**.

6. Under my direction, Analysis Group, Inc. performed some of the work for this report. I am being compensated for my work in this case at the rate of $950 per hour. In addition, I receive a portion of the fees paid to Analysis Group, Inc. for its work. This compensation is not contingent on the nature of my findings or the outcome of this litigation.

II. SUMMARY OF CONCLUSIONS

7. After reviewing the reports of Drs. Kanter, Hay, and Biaett, I find that none of their reports lead me to change the conclusion that I reached in my Initial Report, which was and continues to be that Gilead's HBV speaker and advisory board programs were consistent with government guidelines and industry standards, and did not demonstrate characteristics associated with improper influence on physician prescribing. Specifically, I find the following:

8. *First*, Dr. Kanter's literature review and the studies she cites do not demonstrate a causal relationship between payments and prescribing that would be applicable to this case. Her citations do at times suggest that an *association* (i.e., correlation) may exist between *promotion* and prescribing. However, these studies do not support generally that there is widespread evidence of anything more than correlation, let alone *causation*, between *speaker and advisory*

board program honoraria and increased prescribing. Moreover, none of the studies provide any evidence that they would necessarily apply to HBV drugs. Even if the studies on which she relies could be causally interpreted and did relate to speaker programs and advisory board honoraria, which is not the case, it would be inappropriate to use those studies to reach broad conclusions about Gilead's alleged conduct when an actual direct examination of the facts and data are possible.

9. *Second*, Dr. Kanter's conclusion that Dr. Hay's regression results are "consistent with the academic literature documenting the influence of pharmaceutical firm payments on physician prescribing"[6] is flawed. Dr. Hay's regression results show only an "association" (i.e., correlation) between Gilead's speaker program honoraria and prescribing, which Dr. Kanter concedes, rather than any "influence." In addition, the methodology employed by Dr. Hay to study the association between Gilead's speaker program honoraria and prescribing is highly flawed and none of the academic studies cited by Dr. Kanter employ such a simplistic and flawed approach. For example, as a starting point, the studies to which Dr. Kanter cites at least attempt to account for some factors that may confound the relationship between manufacturer payments to physicians and prescribing. Dr. Hay accounts for essentially no factors in his regression analysis, which makes it striking that Dr. Kanter's assessment of Dr. Hay's findings and approach is that they are somehow consistent with the existing literature. Furthermore, Dr. Hay's regressions do not analyze "subsequent" prescribing upon receipt of honoraria, but instead look at the association between the total of payments and prescribing. As such, Dr. Hay's regression results are meaningless in relation to the question of whether Gilead's speaker and advisory board programs had any impact on physician prescribing. In fact, Dr. Hay makes no

[6] Kanter Report, ¶ 26.

mention of payments influencing or impacting prescribing in his report, stating only that there is a "significant relationship." He specifically states the he has "not reached any conclusions regarding liability in this case and do not offer any opinion in this regard."[7]

10. While Dr. Hay runs a number of analyses examining the relationship between speaker and advisory board payments and prescribing, none of them demonstrate anything beyond correlation between speaker and advisory board program payments and Viread®/Vemlidy® prescribing. In fact, I demonstrate that a regression relating Gilead speaker program payments and prescribing of *non-Gilead* HBV antivirals yields a similar result—certainly Dr. Hay and Relators would not argue that Gilead speaker program payments led physicians to prescribe more *non-Gilead* HBV antivirals.

11. *Third*, Dr. Hay's damages calculations do not rely on these statistical analyses whatsoever, despite the fact that his assignment was to identify prescriptions "arising from and related to" allegedly improper speaker and advisory board payments. Instead, Dr. Hay employs two damages methodologies; in the first, he sums up prescription reimbursements following *any* speaker or advisory board payment, while in the second he only includes payments associated with alleged "sham" events, as identified by Relators' Counsel. Dr. Hay implicitly acknowledges that his first methodology is unreliable because it includes prescriptions that have nothing to do with whether a particular speaker program or advisory board was a "sham" or legitimate. Moreover, neither Dr. Hay nor Relators' Counsel provide information on how these "sham" events were identified or why they should be considered "sham," and there are many instances where there appear to be egregious errors in event identification (e.g., identifying events where a speaker allegedly subsequently attended an event, but it was in fact two different people with the

[7] Hay Corrected Report, ¶ 2, 57.

same name). Assuming certain of Relators' allegations are determined to be accurate, I have estimated that the damages sustained by the Government would be $11.3 million.[8]

12. *Fourth*, the conclusions reached by Dr. Biaett are arbitrary and driven by cherry-picked examples, and do not represent a methodological assessment of whether or not the $125 per person cap set by Gilead was in fact appropriate. Dr. Biaett's threshold of $65 per person is an arbitrary level reached by an undisciplined and simplistic review of certain restaurant websites and does not represent a meaningful distinction from the cap imposed by Gilead. In addition, Dr. Biaett's opinion that the venues for speaker events were intended to be social and entertaining is based on website descriptions that have no relevance to whether or not the venue was appropriate, and his examples are identical to descriptions for venues he describes as "modest" and appropriate.

III. RELATORS' ASSESSMENT OF THE RELATIONSHIP BETWEEN OLP PAYMENTS AND VIREAD®/VEMLIDY® PRESCRIBING IS INACCURATE AND IGNORES THE FACTS OF THIS CASE

13. Dr. Kanter's opinion that Gilead's speaker and advisory board program payments influenced physician prescribing of Viread® and Vemlidy® is based largely on selective portions of literature that she describes as finding a relationship between speaker and advisory board program payments and prescribing. But her reliance on that literature is misplaced, because it ignores (1) the facts of this case that make this literature inapplicable to HBV or Gilead specifically; (2) reasons why these studies do not demonstrate anything more than a correlation between payments and prescribing, and; (3) other literature that comes to the

[8] I understand that any civil penalty, if assessed, would be determined by the Court by multiplying the number of violations by a "civil penalty" adjusted for inflation. In this report, I include estimates that could be used to determine the number of violations. "False Claims Code," 31 U.S.C. § 3729(a)(1), available at https://www.govinfo.gov/content/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3729.pdf

conclusion that the relationship between speaker and advisory board program payments and prescribing is nothing more than mere correlation.

14. Dr. Kanter further concludes that "I found Dr. Hay's finding of a statistically significant positive association between speaker and advisory board program payments to physicians and their subsequent prescribing of Viread® and Vemlidy® consistent with the academic literature documenting the influence of pharmaceutical firm payments on physician prescribing."[9] That conclusion is incorrect for at least two reasons. First, Kanter's reliance on this aspect of Dr. Hay's analysis to establish "influence" is unreliable, because the calculation of Dr. Hay's that she refers to does not attempt to measure "influence," but rather (as Dr. Kanter admits) only "association." Relatedly, the methodology that Dr. Hay uses is far below the methodology in the academic literature to which Dr. Kanter cites in her report, making it striking that Dr. Kanter's assessment of Dr. Hay's findings and approach is that they are somehow consistent with the existing literature. They are not. Second, Dr. Hay's analyses are also grossly deficient on their own terms, and do not demonstrate that there were any Viread®/Vemlidy® prescriptions "arising from and related to paid speaker promotional programs and ad boards conducted by Gilead for Viread® and Vemlidy® for these years."[10] I discuss the deficiencies in both Drs. Kanter and Hay's analyses in this section.

[9] Kanter Report, ¶ 26.1.

[10] Hay Corrected Report, ¶ 2.

A. Dr. Kanter's literature review is not applicable to this case and selectively ignores results that demonstrate speaker and advisory board program payments do not influence physician prescribing

1. *Dr. Kanter's cited academic literature on the association between industry payments and physician activity has very limited, or no, relevant findings*

15. Dr. Kanter provides an overview of several studies that look at the relationship between industry payments and physician activity, such as prescribing, focusing on select studies from a 2020 *Annals of Internal Medicine* paper, which in itself reviewed a set of relevant medical literature. However, there is a fundamental challenge for these studies, because information about the benefits of a drug that may increase prescribing are often presented to physicians at the same time as payments are received. Many of the methodologies used in the studies cited by Dr. Kanter lack the ability to distinguish between the effect on prescribing of information provided to physicians during interactions with pharmaceutical sales representatives and the value of the payment or good provided. Because of this, they conflate the effect of *drug promotion* with the effect of industry payments such as honoraria.

16. Furthermore, many of the studies are subject to confounding factors and simply estimate the *correlation* (which Dr. Kanter sometimes refers to as "association") between industry payments and prescribing, not the *causal* effect of industry payments on prescribing. Correlation can occur when two things happen at the same time, but are otherwise unrelated. As a general matter, mere correlation does not imply causality. And that is especially true in these particular circumstances, as it is well known that industry payments for HCPs with ex ante higher levels of prescribing, and thus more expertise in the relevant treatment area, are not abnormal.[11] In other words, one would expect to see a correlation between payments and

[11] Homer, Patrick, et al., "A Revolution in Physician Targeting," *SAS,* 2009, available at https://alfresco-static-files.s3.amazonaws.com/alfresco_images/pharma/2014/08/21/1cafa74e-5214-4d7a-ab18-08f860a37491/article-612371.pdf.

prescribing, even when payments do not impact prescribing. And so the fact that such a correlation exists (and many of Dr. Kanter's cited studies only find correlation, not causality) does nothing to establish that the payments had an impact on prescribing behavior. Of the few papers that Dr. Kanter cites that do make use of more credible methods, the estimated effects are notably small and suggest that in those particular examples that were studied, the promotion of the studied drug had a relatively small effect on physician prescribing (and as described below, these studies do not look at HBV drugs or similar speaker programs and advisory boards as are at issue here). Within these studies that use more credible methods, which tend to be the newer and more relevant studies, they cannot distinguish between the role of information about a drug's benefits versus the value to physicians of any payment. As such, it is impossible to infer from those studies whether speaker payments lead to more prescribing or whether information about a drug's benefits, that may be unfamiliar to physicians, leads to more prescribing. Additionally, many of the papers Dr. Kanter cites only focus on one or a few drug classes, and oftentimes estimates vary dramatically across drug classes,[12] suggesting that something other than the monetary value of the payment may be driving the results.

17. Dr. Kanter also leaves out studies that did not show consistent impacts of payments on prescribing, which was found in a number of the studies included in the 2021 review article by Mitchell and coauthors.[13] For example, one study found no significant

[12] *See* DeJong, Colette et al., "Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries," *Jama Internal Medicine,* 2016, Vol.176(8), pp. 1114-1122; Fleischman, William et al., "Association of Pharmaceutical Manufacturer Payments to Physicians and Prescribing Dosages of Opioids," *Journal of General Internal Medicine,* 2019, Vol.34(7), pp. 1074-1076; Larkin, Ian et al., "Association Between Academia Medical Center Pharmaceutical Detailing Policies and Physician Prescribing," *JAMA,* 2017, Vol.317(17), pp. 1785-1795; Agha, Leila and Dan Zelter, "Drug Diffusion Through Peer Networks: The Influence of Industry Payments," *NBER Working Paper 26338,* December 2020.

[13] Mitchell, Aaron P. et al., "Are Financial Payments From the Pharmaceutical Industry Associated With Physician Prescribing?" *Annals of Internal Medicine,* 2021, Vol.174(3), pp. 353-361, at p. 356.

difference in the number of prescriptions between physicians that did and did not receive payments.[14] Another study found that only payments associated with educational training programs were correlated with increased prescribing, but that payments for consulting and speakers bureaus (the relevant payments here) were *not* correlated with increased prescribing.[15]

18. Finally, Dr. Kanter's review of these studies and the opinions she forms based on them would imply that *any* payments to prescribers will influence prescribing behavior. Such an interpretation is counter to the OIG and PhRMA guidance, which accept that payments of a fair market value can be acceptable.[16] In the 2003 OIG guidance, OIG stated that "fair market value payments to small numbers of physicians for *bona fide* consulting or advisory services are unlikely to raise any significant concern."[17] The guidance further stated that "compliance with the PhRMA Code with respect to these arrangements [such as providing meals] should substantially reduce a manufacturer's risk."[18] As I discussed in Section V of my Initial Report, Gilead's HBV speaker and advisory board programing was consistent with both the OIG and PhRMA guidelines.[19]

---

[14] Bandari, Jathin et al., "The lack of a relationship between physician payments from drug manufacturers and Medicare claims for abiraterone and enzalutamide," *Cancer*, 2017, Vol.123(22), pp. 4356-4362, at p. 4356.

[15] Yeh, James S. et al., "Association of Industry Payments to Physicians With the Prescribing of Brand-name Statins in Massachusetts," *JAMA Internal Medicine,* June 2016, Vol.176(6), pp. 763-768, at p. 765.

[16] Duke, Elizabeth, "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," Department of Health and Human Services: Office of Inspector General, Federal Register, Vol. 68, No. 86, May 5, 2003, pp. 23731-23743; "Code on Interactions with Healthcare Professionals," *PhRMA*, July 2008, at pp. 3, 7-10, available at https://tinyurl.com/zu4cfurw.

[17] Duke, Elizabeth, *supra* note 16, at p. 23738.

[18] Duke, Elizabeth, *supra* note 16, at p. 23738.

[19] Initial Report, ¶¶ 14, 70-74.

2. *Response to academic literature on whether industry payments influence physician prescribing*

19. In forming her opinion that Gilead speaker and advisory board program payments influenced physician prescribing of Viread® and Vemlidy®, Dr. Kanter reviews seven empirical studies on the effect of industry payments on prescribing behaviors, focusing on studies "that deploy empirical strategies considered by economists to be most persuasive in establishing causation."[20] All but one of these studies were identified based on a 2021 review article by Mitchell et al., which included an additional 30 studies which Dr. Kanter did not include in her report. In this review article, nearly 20% of the studies showed mixed results, suggesting important heterogeneity (i.e., variability) in whether physician prescribing is influenced by industry payments. Of the studies that did not show mixed results, more than two thirds were rated as having a "serious" risk of bias, including three that Dr. Kanter included in her review.[21] This is consistent with a previous review article which reviewed the academic literature from 1992 to August 2016 and reported that all studies "were subject to risk of bias related to the lack of validity of outcome measurement and inadequate handling of significant potential confounders."[22]

20. Furthermore, Dr. Kanter notes that "[t]he academic literature and its findings are robust to a wide range of drugs and drug classes,"[23] but this is incorrect for two primary reasons. First, none of the studies Dr. Kanter reviews are specific to HBV products, let alone Gilead's

---

[20] Kanter Report, ¶¶ 11.1.1, 17.

[21] Mitchell, Aaron P., et al., *supra* note 13, at p. 357, appendix figure.

[22] Fickweiler, Freek, et al., "Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review," *BMJ Open,* 2017, Vol. 7(9), pp. 1-12, at p. 10.

[23] Kanter Report, ¶ 27.

HBV products, and as I described below, the findings do differ across drugs. Dr. Kanter, however, does not acknowledge that the literature she cites might not be analogous to this case, nor does she provide an explanation for why she believes their findings are applicable here. A rigorous and reliable literature review requires some benchmark or metric by which one can evaluate whether a prior study is applicable to the present situation.[24] Dr. Kanter provides none.

21. Second, Dr. Kanter's conclusion is unsupported, in that she draws a direct causal link between Gilead's payments and prescribing based solely on studies that do not apply to HBV, do not apply to Gilead, do not find a reliable and meaningful causal relationship, and layers on to this Dr. Hay's flawed, correlational analysis. To the extent that the academic literature does identify any small relationship between payments and prescribing for certain drugs, other factors beyond payments also play a role—none of Dr. Kanter's cited studies show a meaningful effect that would clearly translate to Gilead's programs or HBV drugs. Furthermore, the literature estimates average effects, which do not necessarily apply to all doctors and all settings. In order to appropriately assess whether there was any impact of the Gilead Opinion Leader Program ("OLP") on prescribing in this matter, one would have to find empirical evidence that goes beyond a simple correlation between Gilead's payments and Viread® and Vemlidy® prescribing. The academic literature cited by Dr. Kanter and Dr. Hay's regression analysis do not attempt nor accomplish this.

22. DeJong and coauthors use cross-sectional data to estimate only a correlation, not a causal relationship, between physicians that received industry-provided meals and prescribing of

[24] For example, common criteria for determining whether to include or exclude studies from a literature review include limiting to studies with specific participants (e.g., physicians likely to prescribe HBV drugs), or limiting to participants that received certain exposures (e.g., payments for services related to speaker programs or advisory boards as opposed to detailing visits). *See* "Common Inclusion/Exclusion Criteria," *The University of Melbourne,* April 29, 2021, available at https://unimelb.libguides.com/c.php?g=492361&p=3368110.

the promoted drug in four different drug classes.[25] The associations also vary substantially across drug classes.[26] In addition, Dr. Kanter leaves out the fact that the result does not hold for one of the four drugs studied, Pristiq, suggesting important heterogeneity across drugs.[27]

23. Fleischman and coauthors show that opioid-related payments to physicians are correlated with increased probability that the physician prescribes higher opioid *dosages*, and does not evaluate any association with increased prescribing of the at-issue drugs.[28] Importantly, this study does not focus on any one specific drug and includes both brand and generic drugs. This study therefore does not distinguish between whether opioid-related payments from a specific manufacturer increase prescribed dosages of the promoted drug, or whether physicians that receive opioid-related payments prescribe higher levels of all opioids to begin with. Given that the study is only designed to estimate a correlation, and not a causal effect, it is just as likely that the findings are actually the result of opioid-related industry payments targeting physicians that treat patients who are more likely to use opioids and are therefore more likely to prescribe higher levels and dosages of opioids irrespective of any payments. Furthermore, the opioid drug class is unique and complicated by the opioid epidemic and increased tolerability from patients. Certainly, drugs with the potential for addiction or abuse, and where patient use may increase

---

[25] According to the authors, "the findings reflect an association, and not necessarily causality." The drug classes studied include statins, beta blockers, ACE inhibitors/ARBs, and SSRIs/SNRIs, none of which includes HBV drugs. *See* DeJong, Colette et al., *supra* note 12, at pp. 1114, 1121; Kanter Report, ¶ 22.1.

[26] Depending on the drug class, the odds of prescribing a promoted drug were between 1.18 and 2.18 times the odds of prescribing a competing drug, implying that the effects were nearly twice as big for some drugs as they were for others. *See* DeJong, Colette et al., *supra* note 12, at p. 1114.

[27] DeJong and coauthors additionally test whether receipt of costlier meals, defined as those above $20, is significantly associated with increased prescribing and find that this relationship holds for only three of the four drugs studied. *See,* DeJong, Colette et al., *supra* note 12, at pp. 1115, 1119.

[28] This study is limited to the opioid drug class. *See* Fleischman, William et al., *supra* note 12.

quickly, have unique considerations. Therefore, results based on opioids likely do not generalize to other drugs, particularly HBV drugs.

24. Larkin and coauthors use restrictions on pharmaceutical detailing at academic medical centers ("AMCs") to show that exposure to restrictive detailing policies is correlated with a 1.67 percentage point decrease in physician-specific market share of detailed drugs.[29] Importantly, the authors cannot rule out an information story: that is, when detailing policies were restricted, physicians did not receive meals *or* the beneficial information on the drug conveyed through detailing, so the effect could be the result of no longer learning about the drugs. In fact, there were two (out of nineteen) AMCs where only a restriction on gifts was put into place, but not a restriction on sales representatives' access to physicians. In these gift-restricted AMCs, one could argue that the reduced prescribing may be due to payments alone. However, in both AMCs the change in market share, which was a 0.65 percentage point decrease for Northwestern and a 1.23 percentage point decrease for Thomas Jefferson, was not statistically significant.

25. A related limitation is that the level of detailing in each AMC before and after the restrictions were implemented is unknown to the researchers. Therefore, it is impossible to say whether the policies were enforced or whether they led to any meaningful change in the amount of detailing a physician was exposed to. Because of this, it is also possible that the authors are picking up the effects of other concurrent changes that also affected physician prescribing. Additionally, the reduction in prescribing of detailed drugs varied significantly across different drug classes, and in two of the drug classes the results were not significant and the coefficient

[29] Target drug classes included 22 lipid-lowering drugs, 15 gastroesophageal reflux disease drugs, 46 diabetes drugs, 69 antihypertensive drugs, 17 hypnotic drugs approved for the treatment of insomnia [sleep aids], 16 attention-deficit/hyperactivity disorder drugs, 55 antidepressant drugs, and 22 antipsychotic drugs. *See* Larkin, Ian et al., *supra* note 12, pp. 1785-1795 and eTable 2 (supplementary online content); Kanter Report, ¶ 23.1.

was actually positive. The results also varied across specific AMCs, with significant results for detailed drugs in only nine out of the nineteen AMCs, and significant results for *non-detailed drugs* in 8 AMCs, suggesting important heterogeneity across both physicians and drugs. Finally, the estimated effect of 1.67 percentage points is off a base of 40 percent, so the effect is relatively small and highlights that of the many factors that influence physician prescribing (including patient need, physician experience, etc.), the impact of physician payments, if any, is very small.

26. In the study by Parker-Lue, which Mitchell and coauthors rate as having a "critical" risk of bias, the author finds that a reduction in payments by the pharmaceutical company GSK did *not* lead to a decrease in overall in-hospital, branded prescribing.[30] While Dr. Kanter does provide valid criticism of this study, particularly that it does not distinguish between prescribing of GSK products versus other branded products, Dr. Kanter also criticizes it for focusing on inpatient drugs, which she claims are a small share of all drugs and which many physicians do not prescribe. However, this description also characterizes HBV drugs, which are also a small share of all drugs. Consequently, it is unclear how any of the other studies Dr. Kanter puts forth would be generalizable to the HBV market by this same metric.

27. In the study by Brunt, the author finds that industry payments are correlated with a three percent higher annual Medicare prescription drug cost per beneficiary, and 0.3 percent higher total share of prescription costs attributable to branded drugs.[31] A major flaw of this study is that prescribing and payments are not broken out by drug. Because of this, an increase in

---

[30] Mitchell, Aaron P. et al., *supra* note 13, appendix figure; Parker-Lue, Sara, "The Impact of Reducing Pharmaceutical Industry Payments on Physician Prescribing," *Health Economics*, 2020, Vol.29(3), pp. 382-390; Kanter Report, ¶ 23.2.

[31] Brunt, Christopher Scott, "Physician Characteristics, Industry Transfers, and Pharmaceutical Prescribing: Empirical Evidence from Medicare and the Physician Payment Sunshine Act," *Health Services Research,* 2019, Vol.54(3), pp. 636-649; Kanter Report, ¶ 24.1.

prescribing of one brand drug that coincides with receipt of payment from a different brand manufacturer could be erroneously perceived as an effect of the payment, despite the fact that the payment was unrelated to the drug that was ultimately prescribed. In the HBV market, this may happen if speaker programs increase a physician's overall knowledge of HBV, leading them to identify, treat, and prescribe more HBV brand-name drugs, regardless of manufacturer. Brunt's estimates that Dr. Kanter presents in her report use physician fixed effects, which controls for differences across physicians in baseline levels of prescribing. However, the study also provides estimates that do not use physician fixed effects. These estimates are up to 12 times as large as the estimates that use physician fixed effects, providing critical evidence that physicians who treat more patients that may benefit from the relevant drug (and therefore have pre-existing overall higher prescribing rates and/or more expensive prescribing) tend to have the expertise that manufacturers seek out for paid programs. As I discuss in Section III.C.3, Dr. Hay's regression analyses do not use physician fixed effects.

28. The study by Agha and Zeltzer uses an event study design with physician-drug fixed effects to show that in each quarter with a compensation payment, the number of prescription fills increases by 0.37 patients.[32] While the method does allow them to get around some issues of endogeneity, the estimated effect is extremely small—equal to each payment-receiving physician prescribing to *only a single additional patient* on average over the course of a year. Additionally, the authors focus on a single drug class, anticoagulants, analyze only three drugs (Xarelto, Eliquis, and Pradaxa) in that class, and focus on a period when a new generation of anticoagulants was being introduced. Because of this, their results are not generalizable to

[32] Agha, Leila and Dan Zelter, *supra* note 12, ¶ 24.2.

other drug classes, particularly to HBV drugs like Viread® that had been long-established and programs like Gilead's that were intended to reach an underserved population.

29. The study by Carey and coauthors uses a similar design to the study by Agha and Zeltzer and finds that receipt of payment by physicians may have some small effect on physician prescribing. [33] However, the effect of payments cannot be separated from the effect of physician education because payments (or in-kind payments) are very often provided for attendance at educational events, and thus concurrent with education itself. In fact, the authors find similar effects if they limit their analysis to just lower-value payments. As Dr. Kanter herself seems to acknowledge, the fact that higher- and lower-value payments have a similar (small) effect on prescribing makes it impossible to rule out the "alternative hypothesis that the clinical and product information conveyed during a meal led to increased prescribing."[34] Dr. Kanter goes on to state that "[t]his is because the educational content of a program with an incidental meal should be the same" no matter the payment amount.[35] If two programs with identical content, but differing payments, result in similar changes in prescribing behavior, that change could just as likely (or indeed, more likely) be caused by the educational content as by the payments. This is further supported by the authors' finding that payments have no effect on the quality of prescribing, indicating that payments cannot be used to persuade physicians to prescribe low-efficacy drugs, which we would likely see if the payment itself was driving prescribing. In addition to these issues, the effect they do find is extremely small and arguably negligible: in each of the first six months following receipt of payment, the number of patients taking the

---

[33] Carey, Colleen, et al., "Drug Firms' Payments and Physicians' Prescribing Behavior in Medicare Part D," *Journal of Public Economics,* 2021, Vol.197, pp. 1-14; Kanter Report, ¶ 24.3.

[34] Kanter Report, ¶ 18.

[35] Kanter Report, ¶ 18.

marketed drug increased by 0.03 and the number of days supplied increases by 0.9. Given that the authors find an almost negligible effect on prescriptions and no effect on the quality of prescribing, and that their results may in fact be driven by physician education as opposed to payments, this study ultimately shows that payments have no meaningful effect on physician prescribing.

30. Lastly, I note that by Dr. Kanter's own definition, the analysis I describe later in Section III.C.3 constitutes a research design that is "persuasive in establishing causation" because "instead of comparing different physicians, [it] compare[s] the physician against him- or her-self. With this strategy, one first compares the prescribing of a physician after a payment to his/her prescribing prior to the payment."[36] In that analysis, which is described in more detail in Section III.C.3, I find that there is no meaningful causal relationship between speaker program or advisory board program payments and prescribing of Viread® or Vemlidy®.

3. *Response to academic literature on whether industry payment influence can occur without physicians being aware of the influence*

31. Dr. Kanter also reviews the literature on whether industry payments can affect physician prescribing without the physicians being aware of it. While these studies are interesting from a human psychology perspective, they are not applicable to this case as they cannot speak to whether industry payments, rather than information, influence prescribing. Furthermore, the studies Dr. Kanter reviews are not generalizable to Gilead's HBV payments as they are limited to small samples of physicians prescribing a few drugs in a handful of specific geographic areas. Dr. Kanter does not provide a methodology to assess whether such studies are applicable to this case, and simply states that they are relevant. As a threshold matter, it is

[36] Kanter Report, ¶¶ 17, 20.

important to make such an assessment given the conclusions Dr. Kanter draws from these studies on the matter at hand. As I describe more fully below, I do not find that Dr. Kanter's cited studies have a relevant bearing on the question of whether Gilead's speaker and advisory board payments impacted physician prescribing.

32. Dr. Kanter reviews a study by Avorn and coauthors that involves a 40-year-old survey of 85 physicians in Boston. The survey asks these physicians about the sources of information that influence their prescribing decisions for two specific drug classes, cerebral and peripheral vasodilators and propoxyphene.[37] These two drug classes are notable because, at the time, commercial information sources emphasized efficacy and reliability, whereas scientific publications found minimal, if any, efficacy.[38] The authors found that while physicians rated scientific papers as a more important source of information than commercial sources, their beliefs about the specific drug classes were more consistent with the information presented in commercial sources than in scientific sources.[39] Dr. Kanter concludes that this study "highlight[s] an important lack of conscious awareness of the influence of commercial sources on prescribing choices."[40]

33. The Avorn study is not relevant in the current matter because its conclusions are not generalizable: the study involves a small sample of physicians in a single city and focuses on only two drug classes in which the promoted information emphasized outcomes that were not consistent with the scientific literature. These drug classes do not include HBV drugs and they

---

[37] Avorn, Jerry, et al., "Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *The American Journal of Medicine,* July 1982, Vol.73(1), pp. 4-8 at p. 4; Kanter Report, ¶ 29.

[38] Avorn, Jerry, et al., *supra* note 37, at p. 4.

[39] Avorn, Jerry, et al., *supra* note 37, at pp. 6-7.

[40] Kanter Report, ¶ 29.4.

are not similar to the HBV market as the information provided during Gilead speaker programs is directly based on the scientific literature.[41] Furthermore, this study is not relevant to whether payments have any effect on physician prescribing, as the study does not ask any questions about whether physicians received industry payments. The study also does not ask any questions about how these physicians formed the beliefs they held: for example, are these specific beliefs the result of discussions with colleagues, which almost half of physicians rated as being a very important factor, or were the beliefs formed based on interactions with pharmaceutical sales representatives? If the latter, then this study actually shows that information provided during interactions with pharmaceutical sales representatives can result in physicians learning new information. If this information is consistent with the scientific literature, then there is even more reason to doubt the ability to establish anything beyond a correlation between payments and prescribing in that the studies cannot separate payment and education.

34. The study by Orlowski and Wateska suffers from this same problem: the prescribing rates of ten physicians from a single academic medical center were tracked before and after they went on a pharmaceutical company sponsored trip to attend one of two medical symposia, for which they were reimbursed.[42] While the authors find that the prescribing rates of these ten physicians increased significantly following each symposium, they are unable to rule out whether this effect was caused by the trip or by the educational information provided during each symposium. Regardless, the study is not generalizable to the current matter as it focuses on two unnamed drugs prescribed by ten physicians in a single academic medical center.

---

[41] The Gilead speaker program slide decks I reviewed contain numerous references to peer-reviewed academic literature in addition to the FDA approved package insert. *See*, *e.g.,* Gilead_Purcell_00098375; Gilead_Purcell_00006322; Gilead_Purcell_00308509.

[42] Orlowski, James P. and Leon Wateska, "The Effects of Pharmaceutical Firms Enticements on Physician Prescribing Patterns," *Chest,* 1992, Vol.102(1), pp. 270-273, at p. 270; Kanter Report, ¶ 30.

35. The study by Springarn and coauthors found that grand rounds given by a pharmaceutical company employee effectively changed residents' beliefs and made them more likely to choose the promoted manufacturer's drug when it was the appropriate clinical choice, but also when it was the inappropriate clinical choice and there was a cheaper, more appropriate drug candidate.[43] In this study, residents did not receive industry payments, therefore the results again highlight the issues with studies that are unable to differentiate between payments and education. Additionally, this study is not generalizable as only 22 residents attended grand rounds at a single academic medical center, and the drug presented was not an HBV drug. Given the wide variation observed across different drugs and drug classes in other studies, there is no evidence that these results would apply to Viread® or Vemlidy®.

36. The study by Steinman and coauthors finds that physicians believe that they themselves cannot be influenced by pharmaceutical representatives, but that their colleagues can.[44] While this is an interesting finding related to human psychology, it does not provide any information on whether physicians are *actually* influenced by pharmaceutical sales representatives or industry payments.

37. Overall, the studies presented by Dr. Kanter on whether physicians can be unknowingly influenced are irrelevant to the question of whether Gilead's HBV payments had any effect on Viread® and Vemlidy® prescribing and, if so, the extent of that effect.

---

[43] Springarn, Roger W., et al., "When Pharmaceutical Manufacturers' Employees Present Grand Rounds, What Do Residents Remember," *Academic Medicine,* January 1996, Vol.71(1), pp. 86-88, at p. 86; Kanter Report, ¶ 31.

[44] Steinman, Michael A., et al., "Of Principles and Pens: Attitudes and Practices of Medicine Housestaff toward Pharmaceutical Industry Promotions," *American Journal of Medicine,* 2001, Vol.110(7), pp. 551-557, at p. 551; Kanter Report, ¶ 32.

B. Dr. Kanter misinterprets Dr. Hay's regression

38. Dr. Kanter also bases her conclusion that Gilead speaker and advisory board payments influenced physician prescribing of Viread® and Vemlidy® in part on Dr. Hay's regression analysis.[45] She describes Dr. Hay's finding as a "statistically significant positive **association** between speaker and advisory board program payments to physicians and their **subsequent** prescribing of Viread[®] and Vemlidy[®]" [emphasis added].[46] Not only does Dr. Kanter's use of the word "association" imply that Dr. Hay's estimates are nothing more than a correlation (which is all they are), but her description of Dr. Hay's analysis is also incorrect, as Dr. Hay does not estimate the relationship between payments and *subsequent prescribing,* but instead estimates the correlation between prescribing and total honoraria, which includes prescriptions written *before* the honoraria was received.[47] While Dr. Hay includes one set of regressions that are "by year," he only varies prescribing by year, not payments, effectively correlating prescribing in each year with *total* honoraria payments—even for prescriptions written before any payments were received.[48] For example, Dr. Alan Yao received his first (and only) Viread® speaker payments in 2016, a total of $4,000 for two programs. Yet Dr. Hay's regression compares the $4,000 in total payments to the level of Viread® prescribing in each year separately from 2013 - 2019, thus correlating prescriptions written prior to 2016 with future payments, *not* payments with subsequent prescribing, as Dr. Kanter suggests.

---

45 Kanter Report, ¶¶ 11, 11.1.2.

46 Kanter Report, ¶ 26.1.

47 Notably, Dr. Hay's regression analysis also does not imply anything regarding the relationship between advisory board program honoraria and physician prescribing behavior, as he includes only *speaker program* honoraria payments in his analysis. Hay Corrected Report and associated production materials.

48 Hay Corrected Report and associated production materials.

39. Dr. Hay's regression analyses also do not meet Dr. Kanter's criteria for what constitutes a study that is persuasive in establishing causation or anything beyond correlation. Dr. Kanter identifies three methodologies that are "considered by economics to be most persuasive in establishing causation" rather than mere correlation: (1) differentiating between competing hypotheses, such as whether Gilead payments influenced prescribing or Gilead targeted speakers who had significant knowledge from treating a large number of HBV patients, and therefore had higher levels of prescribing to begin with; (2) using a quasi-experimental research design, which "help[s] facilitate an apples-to-apples comparison of physicians"; and (3) comparing the physician against her- or himself before and after receiving payments.[49] Dr. Hay employs none of these methodologies.

C. Dr. Hay's analyses do not demonstrate anything besides correlation and certainly fail to demonstrate that any Viread®/Vemlidy® prescribing was "arising from and related to" OLP payments

40. Dr. Hay includes three groups of analyses that examine the relationship between speaker and advisory board payments and Viread®/Vemlidy® prescribing. In the first group, Dr. Hay calculates Gilead's supposed "return on its investments"[50] ("ROI") for Viread® and Vemlidy® speaker programs. Dr. Hay opines that Gilead's speaker program had an "excellent" ROI by comparing the amount that certain physicians received in speaker program honoraria to the amount of Medicare paid claims submitted by those same physicians.[51] In the second group, Dr. Hay compares the average number of Viread®/Vemlidy® prescriptions written by speakers/advisors to non-speakers/advisors, and demonstrates that, on average, speaker/advisors

[49] Kanter Report, ¶¶ 17 - 20.

[50] Hay Corrected Report, ¶ 50.

[51] Hay Corrected Report, ¶ 50.

write more Viread®/Vemlidy® prescriptions than non-speakers/advisors.[52] In the third group, Dr. Hay runs *single variable* regressions (or just controls for year, albeit incorrectly, as I discuss further below) comparing the level of speaker payments to the level of Viread®/Vemlidy® prescribing, and concludes that an increase in honoraria results in a corresponding increase in Viread®/Vemlidy® prescribing.[53]

41. Dr. Hay's "ROI" calculation shows nothing aside from the fact that speakers prescribe Viread® and Vemlidy® at volumes that result in reimbursements exceeding the cost of engaging them as speakers, and his volume and regression analyses do not demonstrate anything more than correlation between payments and prescribing. Notably, Dr. Hay appears to explicitly avoid stating that these analyses demonstrate a causal relationship between speaker or advisory board payments and Viread®/Vemlidy® prescribing. Indeed, his analyses do not actually test for a causal relationship between speaker and advisory board payments and Viread®/Vemlidy® prescribing, but Dr. Hay nonetheless insinuates one by calculating an "ROI," and making statements such as "each $1000 increase in honoraria ***results in*** a corresponding increase in prescription count by 1.6 per year…"[54] In this section, I describe the gross deficiencies related to these analyses and explain why they do not, in fact, demonstrate any relationship beyond correlation between speaker and advisory board payments and Viread®/Vemlidy® prescribing—much less any causal relationship.

---

52 Hay Corrected Report, ¶¶ 52-55.

53 Hay Corrected Report, ¶¶ 57 - 60, and associated production materials.

54 Hay Corrected Report, ¶ 57 (emphasis added).

1. *Dr. Hay's speaker program "ROI" analysis incorrectly assumes that speakers would not have written any Viread®/Vemlidy® prescriptions*

42. As I discuss extensively in my Initial Report, the purpose of speaker programs was education.[55] While teaching physicians about the benefits of Viread® and Vemlidy® and educating the community on the importance of HBV treatment may result in incremental prescriptions for Gilead in an indirect way, payments to speakers for these programs were not an "investment" intended to induce additional prescribing.

43. From an economic perspective, an ROI is calculated as the difference between the net gain from an investment and the cost of that investment.[56] Importantly, the "gain from an investment" represents the ***incremental*** earnings generated as a result of the investment. Dr. Hay's "ROI" calculation does not do this.

44. First, changes in Gilead's speaker and advisory board payments did not result in incremental Viread® and Vemlidy® prescriptions. Exhibit 15 of my Initial Report assesses the relationship between physician-level annual changes in honoraria payments and prescribing of Gilead products from 2013 to 2019—consistent with one of the methodologies that Dr. Kanter suggests for establishing causation. With a correlation coefficient of 0.08, there is no meaningful

---

[55] Initial Report, Sections III.C, IV.

[56] Phillips, Jack J., "Return on Investment in Training and Performance Improvement Programs," *Routledge*, Second Edition, 2003, p. 21 (ROI = (Net Program Benefits/Program Costs) x 100). *See also* "What is Return on Investment (ROI)," *Corporate Finance Institute*, available at https://corporatefinanceinstitute.com/resources/knowledge/finance/what-is-return-on-investment-roi/ ("ROI = ((Gain from Investment - Cost of Investment)/Cost of Investment)) x 100).

relationship between changes in payments and changes in prescribing at the physician level.[57] I explore this further in Section III.C.3 of this report. This result calls into question whether Gilead was actually capturing a "return" on its "investment" if these physicians were not prescribing additional Viread®/Vemlidy® prescriptions upon receipt of additional payments.

45. Second, Dr. Hay's "ROI" calculation completely fails to consider how much Viread® or Vemlidy® the "Top 10" Viread® and Vemlidy® speakers (as identified by Dr. Hay)[58] would have prescribed absent speaker and advisory board payments; his implicit assumption is that they would not have prescribed any at all. Given that Viread® and Vemlidy® collectively accounted for nearly 65 percent of HBV antiviral prescriptions prior to the period when the generic formulation of Viread® became available, it is not realistic to simply assume that physicians treating hundreds of HBV patients would not have prescribed any Viread® or Vemlidy® absent these payments.[59] This further suggests that Dr. Hay's "ROI" calculation does not accurately capture the "return" (incremental Viread®/Vemlidy® prescriptions) generated by Gilead's alleged "investment" (speaker program payments).

---

[57] *See, e.g.,* Taylor, Richard, EdD, RDCS, "Interpretation of the Correlation Coefficient: A Basic Review," *Journal of Diagnostic Medical Sonography*, January/February 1990, Vol. 6, pp. 35-39, at p. 37, available at https://journals.sagepub.com/doi/pdf/10.1177/875647939000600106, ("It is important to understand that it is possible to obtain a nonzero [correlation coefficient] even when no correlation actually exists… [C]orrelation coefficients (in absolute value) which are ≤ 0.35 are generally considered to represent low or weak correlations, 0.36 to 0.67 modest or moderate correlations, and 0.68 to 1.0 strong or high correlations with *r* coefficients ≥ 0.90 very high correlations."). *See also* Heumann, Christian et al., "Introduction to Statistics and Data Analysis," *Springer*, 2016, p. 83 ("If [correlation is close to zero], then it indicates that the variables are independent or the relationship is not linear.").

[58] [redacted]

[59] Symphony Health Data (accessed on March 18, 2021); "Approved Drugs for Adults," *Hepatitis B Foundation*, available at https://www.hepb.org/treatment-and-management/treatment/approved-drugs-for-adults/; Gilead_Purcell_00224639, Gilead_Purcell_00311272, Gilead_Purcell_00327018, Gilead_Purcell_00340769 ("IMS/IQVIA Prescription Data").

2. *Dr. Hay's comparison of speaker/advisor prescribing to non-speaker/advisor prescribing does not demonstrate a causal relationship between payments and prescribing*

46. In his second group of analyses, Dr. Hay compares the average number of Viread®/Vemlidy® prescriptions written by speakers/advisors to non-speakers/advisors.[60] For example, Dr. Hay finds that "speakers wrote an average of over 15 times the number of prescriptions for Viread[®] compared to non-speakers,"[61] which he concludes is "[f]urther evidence of Gilead's rewarding of high prescribers…"[62] But the only statistical conclusion that one can draw from these comparisons is that, on average, speakers/advisors prescribed more Viread® and Vemlidy® than non-speakers/advisors. Yet, Gilead speakers/advisors also prescribe substantially more non-Gilead HBV antivirals; specifically, speakers prescribe 34 times more than non-speakers, while advisors prescribe 31 times more than non-advisors.[63] Given the educational goals of both the speaker and advisory board programs, this is exactly what I would expect; speakers and advisors who prescribe more HBV antivirals have more experience with Viread® and Vemlidy® and treating HBV patients generally, which is precisely what one would want in an educator.[64]

47. It is also notable that despite the difference in average prescriptions across speakers/advisors and non-speakers/advisors, the non-speaker/advisor group collectively accounts for more than 58 percent of total Viread® and Vemlidy® prescriptions over the at-issue

---

60 Hay Corrected Report, ¶¶ 52 - 55.

61 Hay Corrected Report, ¶ 54.

62 Hay Corrected Report, ¶ 52.

63 Gilead_Purcell_00046904, 00058651, 00075800, 00109300, 00109542, 00109677, 00109731, 00114455, 00114779, 00137107, 00216770, 00216771, 00216772, 00216774, 00224964, 00279007, 00283133 ("Managed Care Report Data")

64 I provided many examples of the substantial, relevant experience of Gilead speakers who received the most honoraria payments over the at-issue period in Section V.C of my Initial Report.

time period.[65] Additionally, there are many non-speakers who prescribe substantial volumes of Viread® and Vemlidy®; the standard errors for Dr. Hay's calculations are very large and the majority exceed the respective average number of prescriptions for both speakers/advisors and non-speakers/advisors, indicating some speakers/advisors do not prescribe high volumes of Viread®/Vemlidy®, and some non-speakers/advisors prescribe high levels of Viread®/Vemlidy®.[66]

3. *Dr. Hay's regression analyses suffer from a number of fundamental limitations that render the results meaningless*

48. Finally, Dr. Hay runs a series of regressions that compare levels of Viread®/Vemlidy® prescribing to the payments provided to speakers. All of Dr. Hay's regressions fail to perform even the most rudimentary steps required to extract meaningful results, and many are fundamentally flawed in their structure. While I have already described how Dr. Hay's results imply only correlation (also known as association) under certain specifications, any basic statistics textbook will explicitly warn that "[r]egression analysis… establishes associations between X_i's and Y, ***not causation***, unless strong assumptions are made" and that "one of the most important assumptions to interpret regression parameters in a causal way is to have measured (and used) all variables X_i which affect both the outcome Y and the variable of interest."[67] Dr. Hay fails to consider or include *any*, let alone all, variables that affect levels of Viread®/Vemlidy® prescribing. Notably, none of the academic studies cited by Dr.

---

[65] IMS/IQVIA Prescription Data; Gilead_Purcell_00278464, Gilead_Purcell_00134582, Gilead_Purcell_00324518, Gilead_Purcell_00327015 ("Speaker Program Spend Reports"); Gilead_Purcell_00134580, Gilead_Purcell_00216563, Gilead_Purcell_00311268, Gilead_Purcell_00327017 ("Advisory Board Spend Reports"). [redacted]

[66] Hay Corrected Report, ¶¶ 52-55.

[67] Heumann, Christian et al., *supra* note 57, p. 288 (emphasis added).

Kanter employ such a simplistic and flawed approach.[68] For example, as a starting point, the studies to which Dr. Kanter cites at least attempt to account for some factors that may confound the relationship between manufacturer payments to physicians and prescribing. Dr. Hay accounts for essentially no factors in his regression analysis.[69]

49. In particular, Dr. Hay's regressions compare speaker program payments to Viread®/Vemlidy® prescribing without controlling for any patient-specific or physician-specific factors that would impact prescribing levels. For example, it would be expected that gastroenterologists and hepatologists would prescribe higher volumes of Viread®/Vemlidy® (I demonstrate this in Exhibit 5 of my Initial Report). Furthermore, it is also likely that gastroenterologists and hepatologists would be engaged by Gilead as speakers because they specialize in treating liver diseases such as HBV. Without controlling for these physician-specific factors, Dr. Hay's regressions demonstrate only that many of Gilead's speakers who received the most honoraria payments were experienced Viread®/Vemlidy® prescribers. Later in this Section I demonstrate the impact of controlling for physician fixed effects in order to more accurately test if speaker program payments had any relationship with subsequent physician prescribing of Viread® and Vemlidy® beyond correlation.

50. To demonstrate the inaccuracy of Dr. Hay's regression interpretation, I ran a comparable series of regressions that replace Viread®/Vemlidy® prescriptions with non-Gilead HBV antiviral prescriptions as the dependent variable. Exhibit 1 reports the results of these regressions. I ran these analyses using both of Dr. Hay's approaches—"by year" and "all time."[70] Similar to Dr. Hay's analyses, there is a positive and statistically significant correlation between

---

[68] Kanter Report, ¶¶ 22-24.

[69] Hay Corrected Report, ¶¶ 57 - 60, and associated production materials.

[70] Hay Corrected Report, ¶¶ 57 - 60.

total Gilead speaker program payments and number of *non-Gilead* HBV antiviral prescriptions. This is not surprising given that Gilead engaged speakers who treat many HBV patients and thus prescribe relatively higher levels of many HBV antiviral drugs (not just Gilead drugs), but it would be inaccurate (and illogical) to interpret this correlation as Gilead speaker program payments causing these physicians to increase prescribing of *non-Gilead* HBV antiviral products.

Excerpt of Exhibit 1[71]

Viread/Vemlidy Honoraria Payments and Prescribing of Non-Gilead HBV Antivirals Among Speakers

Prescription Counts of Non-Gilead HBV Antivirals by Year			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	64.0846	18.3419	0.0005
Viread Honoraria	0.0030	0.0003	<.0001
Year	-5.4384	5.3682	0.3113

Prescription Counts of Non-Gilead HBV Antivirals by Year			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	73.7308	22.4330	0.0011
Vemlidy Honoraria	0.0110	0.0009	<.0001
Year	-11.3112	5.9947	0.0596

All Time Prescription Counts of Non-Gilead HBV Antivirals			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	227.7615	80.0587	0.0048
Viread Honoraria	0.0031	0.0006	<.0001

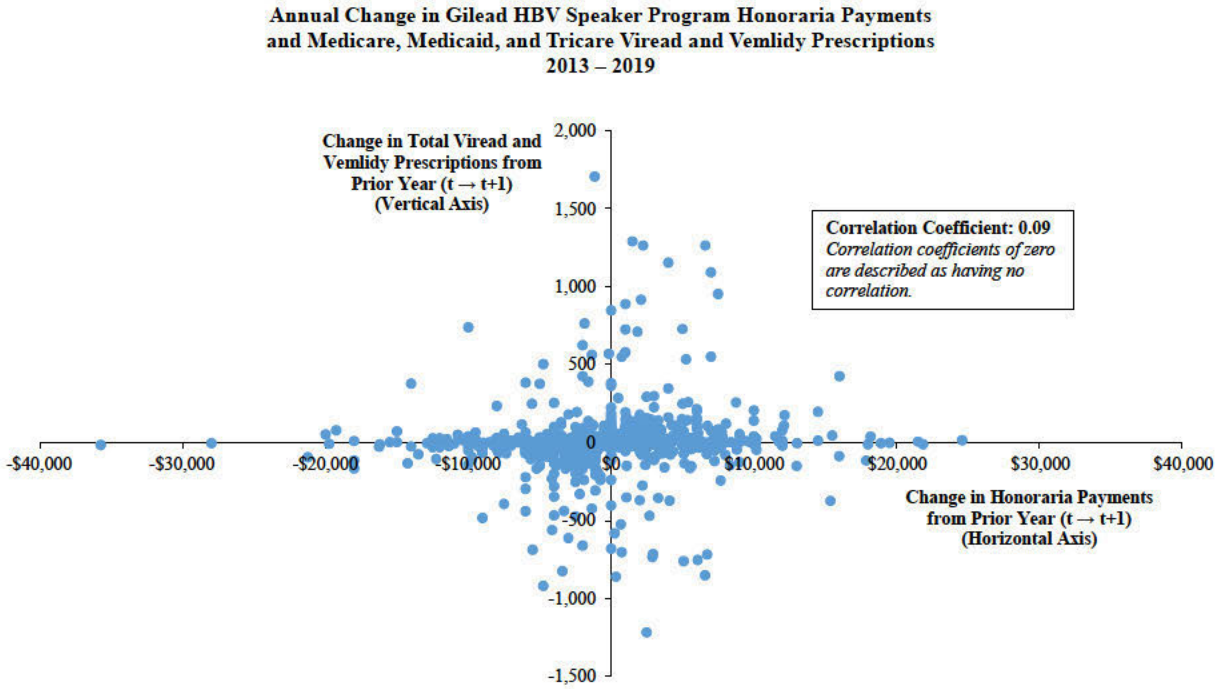
All Time Prescription Counts of Non-Gilead HBV Antivirals			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	143.1715	104.0837	0.1708
Vemlidy Honoraria	0.0115	0.0017	<.0001

51. In order to extract any meaningful implications related to causation using regression analysis, it is necessary to control for other physician attributes that impact the level of Viread® and Vemlidy® prescribing, and control for the timing of payments relative to prescriptions. In my Initial Report, Exhibit 15 tests whether there is a correlation between the

[71] Non-Gilead HBV antiviral prescribing is measured using the Managed Care Report prescription data from 2013 - Q2-2017 and is compared to Viread®/Vemlidy® honoraria payments over the same time period. Regressions with Viread® (Vemlidy®) honoraria include speakers who ever received Viread® (Vemlidy®) honoraria payments during 2013-19 based on Dr. Hay's definition. Managed Care Report Data; Hay Corrected Report and associated production materials; IBM Micromedex Red Book Online, available at https://www.micromedexsolutions.com/micromedex2/librarian/.

change in speaker and advisory board program payments and all Viread®/Vemlidy® prescribing at the prescriber level, comparing payments from period t to prescriptions in period t+1. In Exhibit 2, I replicate this analysis using Medicare, Medicaid, and Tricare Viread®/Vemlidy® prescribing and the speaker program honoraria as identified by Dr. Hay and find a similarly negligible correlation of .09. By looking at changes in payments and prescribing volumes for individual prescribers, this analysis effectively controls for individual prescriber attributes. In other words, it determines whether an *incremental* payment leads to *incremental* prescriptions for individual physicians, rather than simply demonstrating that physicians who prescribe high volumes of Viread® and Vemlidy® are more often engaged as speakers, which is all Dr. Hay's regressions show. Ultimately, the results of Exhibit 2 also confirm that Gilead simply engaged higher volume prescribers as speakers (as Dr. Hay's analyses demonstrate), but that there is no relationship beyond correlation—let alone causation—when one actually tests whether changes in payments caused changes in prescribing rates.

Excerpt of Exhibit 2[72]



52. Exhibit 3 reports results from regression analyses that similarly control for prescriber fixed effects and lag payments relative to prescribing.[73] Note that in his "by year" approach, Dr. Hay treats 'Year' as a continuous variable rather than a categorical dummy variable. The use of a continuous 'Year' variable in a linear regression implies that, year over year, there must be a consistent, linear pattern; categorical year indicators, which I use in my

[72] This analysis is limited to HCPs that received honoraria payments. This analysis excludes years where both the change in total honoraria and total prescriptions from the prior year are zero. Honoraria payments include payments from speaker events. CMS Medicare Part D Prescription Drug Event Data; CMS Medicaid claims data; Tricare data; Hay Corrected Report and associated production materials.

[73] Dr. Hay's attempt to regress "by year" (Hay Corrected Report, ¶ 56) suffers from a number of detrimental errors that I correct in my sensitivities. First, as discussed above, Dr. Hay relies on a continuous 'Year' variable rather than using categorical dummy variables. Second, Dr. Hay varies prescriptions by year, but compares annual prescriptions to the *total* payments a physician received. This implies that payments in later years retroactively impact prescriptions written in earlier years, which intuitively does not make sense. Furthermore, this does not reflect Dr. Hay's damages methodology, which only considers prescriptions to be at-issue if they occur following a specified speaker or advisory board program payment. Hay Corrected Report, ¶¶ 26, 57, and associated production materials.

sensitivities, allow the regression to control for significant events that occurred in a given year, such as the availability of the generic formulation of Viread® in 2017, without consideration of when that year occurred relative to other years in the analysis.[74] Comparable to what I found in Exhibit 2, there is no meaningful causal relationship between speaker program payments and subsequent Viread®/Vemlidy® prescribing; the coefficients on lagged payments are not statistically significant.[75]

[74] Wooldridge, Jeffrey M., "Introductory Econometrics A Modern Approach," *South-Western Cengage Learning,* 2012, Fifth Edition, pp. 235-236, 238, ("We can use several dummy independent variables in the same equation[…] If the regression model is to have different intercepts for, say, *g* groups or categories, we need to include *g* - 1 dummy variables in the model along with an intercept. The intercept for the base group is the overall intercept in the model, and the dummy variable coefficient for a particular group represents the estimated difference in intercepts between that group and the base group…[In an example that looks at the impact of credit rating on municipal bond interest rates] the movement between each credit rating is allowed to have a different effect, so using [dummy variables] is much more flexible than simply putting [credit rating] in as a single variable."). In this case, the movement between each year should be allowed to have a different effect on expected prescribing; for example, the change in Viread® prescribing from 2016 to 2017 due to the availability of the generic formulation of Viread® should not be forced to have the same impact on expected prescribing Viread® prescribing from 2013 - 2014, when no substantial changes occurred in HBV antiviral availability.

[75] Dr. Hay also completes a regression where he purports to compare speaker program honoraria to Medicare plan paid amount (*see* Hay Corrected Report, ¶¶ 57 - 60). But Dr. Hay does not, in fact, compare to Medicare plan paid amount—he includes paid amounts from Medicaid and Tricare, as well. Given that the data he relies on includes different payors for different years (Medicare from 2013 - 2019, Medicaid from 2015 - 2018, and Tricare from 2013 - 2018), it is meaningless to compare total average paid amount over time, as the mix of payors (who all have different payment structures) does not remain consistent. Hay Corrected Report and associated production materials.

Excerpt of Exhibit 3[76]

Viread and Vemlidy Regressions with Fixed Effects and Lagged Honoraria Payments

Viread by Year			
Prescription Counts			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	36.1215	18.3591	0.0502
Lagged Honoraria Payments	0.0019	0.0024	0.4429
Year Indicators			
2015	20.4612	4.6399	<.0001
2016	149.2117	19.2098	<.0001
2017	107.4488	15.8281	<.0001

Vemlidy by Year			
Prescription Counts			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	111.9960	11.3561	<.0001
Lagged Honoraria Payments	-0.0001	0.0011	0.9111
Year Indicators			
2018	78.8816	12.5040	<.0001
2019	-1.2891	13.8316	0.9259

53. Ultimately, neither Dr. Kanter's literature review nor Dr. Hay's analyses demonstrate anything aside from correlation between speaker and advisory board program payments and prescribing. Dr. Kanter relies on cherry picked articles, most of which are inapplicable to this case and do not actually demonstrate anything aside from correlation between promotional payments and prescribing. Dr. Hay's analyses are grossly deficient and simply demonstrate that participants in speaker and advisory programs have substantial experience in prescribing Viread® and Vemlidy®.

IV. DR. HAY'S DAMAGES CALCULATIONS ARE NOT RELIABLE

54. In Section III, I discuss how Drs. Kanter and Hay fail to demonstrate anything beyond correlation between speaker or advisory board payments and Viread® and Vemlidy® prescribing. Furthermore, robust statistical analyses clearly demonstrate that there is no causal

[76] Physician fixed effects are applied to both regressions to account for unobserved physician characteristics that are constant over time. Robust standard errors clustered at physician level are used. Lagged honoraria payments are defined as Viread® or Vemlidy® honoraria payments in the previous year. Corrected Hay Report and associated production materials.

relationship between speaker or advisory board payments and Viread® and Vemlidy® prescribing. Even assuming for the sake of argument that Relators have demonstrated that some of the honoraria payments to speakers and advisors were kickbacks, Dr. Hay's damages calculation is flawed and unreliable. Dr. Hay includes multiple damages approaches that contradict one another, he relies entirely on assumptions and lists of "sham" speaker programs provided by Relators' Counsel, and he does not include any assessment or explanation of why advisory boards were improper. Furthermore, Dr. Hay's reliance on Counsel leads him to ignore important variations across speaker programs and include events that should not be considered "sham." In this section, I discuss the details and implications of these flaws, as well as a number of other errors and shortcomings in Dr. Hay's calculations.

A. Dr. Hay's "damages" calculation is an exercise in addition based on faulty assumptions provided by Relators' Counsel

55. Dr. Hay indicates that his assignment is to calculate "alleged illegal payments and resulting damages… ***arising from and related to*** paid speaker promotional programs and ad boards conducted by Gilead…"[77] But Dr. Hay's damages calculation does not do this; he simply sums up prescription reimbursements following allegedly improper payments identified by Relators' Counsel.

56. In Section III above, I demonstrated that, at most, Dr. Hay's statistical analyses indicate a correlation between OLP payments and Viread®/Vemlidy® prescribing. Dr. Hay does not demonstrate that *any* prescriptions were "arising from and related to" the Gilead OLP programs, or even look specifically at the correlation between "sham" programs and Viread®/Vemlidy® prescribing. Furthermore, the correlation analyses that Dr. Hay does

[77] Hay Corrected Report, ¶ 2.

complete are entirely disconnected from his damages assessment. He does not use the coefficients he calculates in his regression to identify supposedly *incremental* prescriptions. For example, despite claiming (incorrectly), that "each $1000 increase in honoraria results in a corresponding increase in prescription count by 1.6 per year," [78] Dr. Hay counts *all* prescriptions following allegedly improper payments in his damages calculation, rather than the 1.6 prescriptions per $1,000 in payments identified by his regression.[79]

57. While Dr. Hay includes his correlation analyses in his "Damages Calculation Methodology" section, they are not part of his damages methodology. Dr. Hay's damages "methodology" is limited to summing Medicare, Medicaid, and Tricare reimbursements following speaker and advisory board payments identified by Relators' Counsel.[80] The results of these correlation analyses have no bearing on his approach to calculating damages, and there is no indication that his damages estimates would have differed in the event that the analyses yielded different results.

B. Dr. Hay's multiple approaches to calculating speaker program damages are inconsistent with one another

58. Dr. Hay includes two "damages" scenarios for speaker programs: one that considers all speaker program payments improper, and a second that only focuses on a subset of "sham" speaker programs identified by Relators' Counsel. For both speaker program scenarios and his advisory board damages, Dr. Hay calculates sensitivities that include prescriptions

[78] Hay Corrected Report, ¶ 57.

[79] Hay Corrected Report, ¶ 44, and associated production materials.

[80] Hay Corrected Report, Section VI.

written by speakers or advisors following said programs in perpetuity, and prescriptions written in the 12-month, 6-month, or 3-month periods following the programs.[81]

59. Dr. Hay's first approach simply adds up government reimbursements for prescriptions following a speaker's first speaker payment.[82] Because his second approach characterizes only a subset of the speaker programs as "sham," Dr. Hay implicitly acknowledges that his first methodology is unreliable because it includes prescriptions that have nothing to do with whether a particular program was a "sham" or legitimate. Dr. Hay does not provide an opinion on which damages calculation he believes is correct.

60. Furthermore, Dr. Hay relies entirely on Relators' Counsel to identify alleged "sham" speaker program events. He does not assess whether any of these specific events had an impact on physician prescribing, and incorporates untested assumptions provided by Relators' Counsel that are not supported by the data or documents in this case. Later in this section, I examine the various "sham" event categories and how each one contributes to Dr. Hay's damages calculation. Additionally, I discuss a number of factors that Dr. Hay's damages calculation fails to account for and include the impact of each of these factors. Given that Dr. Hay's "sham" events damages approach discredits his "all programs" approach, I base all discussed adjustments on his "sham programs," 3-month damages approach.[83]

C. Dr. Hay and Relators do not reliably identify "sham" events

61. Dr. Hay indicates that his "sham" damages assessment is based on the identification of specific events identified by Relators' Counsel and "defined by other experts

---

[81] Hay Corrected Report, ¶ 22.

[82] Hay Corrected Report, ¶ 22.

[83] I reserve the right to perform additional calculations for other scenarios to the extent the Court determines an alternative scenario is more appropriate.

and the evidence produced by Gilead."[84] Yet Dr. Hay's list of "sham" events includes events that are not on the lists provided by Relators' Counsel,[85] and the "sham" categories identified by Counsel are not consistently supported by other experts.[86] Moreover, Relators' Counsel and Dr. Hay fail to provide a clear methodology for how to identify specific events that fall into the "sham" categories, and a review of the events included demonstrates many examples of events that do not appear to consistently meet the Relators' "sham" criteria.

62. Below, I outline the different "sham" categories included by Relator's Counsel and Dr. Hay, and address the conceptual and methodological flaws with each:

1) *Programs at which the average cost of a meal was over $65 per person*.[87] As I discuss in Section V below, the $65 attendee meal spend limit is arbitrary and counter to industry standards. Indeed, [redacted]—Relator Groome's subsequent employer, which she testifies held legitimate events.[88]

---

84 Hay Corrected Report, ¶ 26.

85 Dr. Hay includes two programs in his list of "sham" events that are not included in the lists provided by Relators' Counsel (event IDs 8039604 and INT-0025323).

86 For example, while Dr. McMahon indicates that "[i]f there are very few learners (***less than 3***) there is likely to be very little or no engaged conversation, little opportunity to share multiple perspectives, and the tutor is quickly dominant," Relators' Counsel and Dr. Hay categorize events as "sham" if they have fewer than ***four*** prescribers present. *See* Expert Report of Dr. Graham McMahon, May 3, 2021 (hereafter "McMahon Report), ¶ 65 (emphasis added) and Hay Corrected Report, ¶ 26. Additionally, Dr. McMahon indicates that "it is unlikely that events where the same or substantially the ***same group of clinicians*** are invited repeatedly to dine together in a restaurant, ostensibly to discuss the same subject matter at each such event, are actually convened for an educational purpose," yet Relators' Counsel and Dr. Hay include events as "sham" if even ***just a single member of a group*** is in attendance at an event. *See* McMahon Report, ¶ 62 (emphasis added) and Plaintiff-Relators' Objections and Supplemental Response to Interrogatories 2,5,9, and 10 of Defendant's First set of Interrogatories, May 12, 2021 (hereafter "First Set of Interrogatory Responses"), Exhibits 7 and 8.

87 Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 3.

88 [redacted]. Transcript from Deposition of Kimberly Groome, April 10, 2021, p. 348:6-11.

Furthermore, the list provided by Counsel and relied on by Dr. Hay related to this category of events includes more than 200 events where the Attendee and Speaker Spend Data clearly demonstrate that the average meal cost did not exceed $65.[89]

2) *Programs at which a speaker was in attendance after having served as a paid speaker.*[90] As I discuss in my Initial Report, from a physician's perspective there can be substantial value in attending speaker programs conducted by other physicians. Each physician has unique experiences with different patients. Hearing about these experiences, perceptions, and lessons from other physicians is the very purpose of such speaker programs and can provide valuable points of reference for a physician's own future presentations.[91]

Furthermore, the list provided by Relators' Counsel and relied on by Dr. Hay misidentifies programs at which a speaker was in attendance after having served as a paid speaker by assuming different people with the same name are the same person. For example, Relators' Counsel identify seven allegedly "sham" events related to the attendance of a Dr. Mark Li of Hacienda Heights, CA.[92] But Dr. Mark Li of Hacienda Heights, CA never served as a speaker—Dr. Mark Li *of Wheaton, Maryland* spoke at a Gilead event on May 24, 2017. Gilead data and

---

89 I provide a list of these 202 events in Appendix 1.

90 Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 1.

91 Initial Report, ¶ 104.

92 First Set of Interrogatory Responses, Exhibit 1, see events INT-0026508, INT-0025778, INT-0023963, INT-0019708, INT-0018986, INT-0010901, INT-0009958. Speaker Program Spend Reports.

publicly available sources, such as Open Payments, clearly identify these as two different individuals, yet Relators' Counsel treat them as the same person.[93]

Additionally, there are numerous examples of instances where a speaker was attending a program introducing Vemlidy® after having previously spoken at unbranded or Viread® events. Given that Vemlidy® was a new drug, there is no reason a speaker for an unbranded or Viread® event should be precluded from attending, or for this event to be deemed a "sham" because of their attendance. For example, Dr. Sonja Olsen attended a Vemlidy® program on December 13, 2016; Dr. Olsen had only spoken at a single Gilead program prior to this date: an unbranded HBV program on January 31, 2013, more than three years earlier.[94]

Finally, prior to 2016, Gilead's Business Conduct Manual did not have any restrictions on the number of times an attendee was permitted to attend its HBV speaker programs.[95] 473 of the 703 events that Relators' Counsel identify in this "sham" category occurred prior to 2016. Gilead began regulating speaker attendance in 2016, but notably the regulations only applied to attendance for topics a speaker was certified to present on. In 2016, Gilead's Business Conduct Manual indicated that "[f]or ***topics a Speaker is certified to present*** on Gilead's behalf, the Speaker may attend the same program a maximum of two (2) times per

---

93 Speaker Program Spend Reports. Open Payments Data, available at https://openpaymentsdata.cms.gov/physician/828693 and https://openpaymentsdata.cms.gov/physician/106265.

94 Speaker Program Spend Reports. Similarly, Dr. Michael Dao attended program 8055641 about Vemlidy® on December 8, 2016; Dr. Dao had previously only spoken at HBV Unbranded events. Dr. Joseph Lin attended program 8052955 about Vemlidy® on November 21, 2016; Dr. Lin had only spoken at unbranded or Viread® events prior to this date.

95 *See, e.g.*, Gilead 2015 Business Conduct Manual, Gilead_Purcell_00000486, Section VIII.3.

calendar year."[96] Even using an overly inclusive name-matching methodology (which appears to be the approach Relators' Counsel took and will identify two people with the same name as one person), relying on this criteria for programs occurring in 2016 through June 2017 reduces the number of events on this list from 173 to one. In July, 2017, this guidance was updated to say that "Speakers may not attend any Speaker Bureau programs ***for topics from the Speaker Bureau in which they are trained***, except by prior approval from Sales Management and Business Conduct."[97] Relying on this criteria for programs occurring from July 1, 2017 onward reduces the number of events on this list from 57 to 7. Taken together, these criteria reduce the number of programs on this list from 703 events to 8 events.[98]

3) *Programs at which a non-medical spouse or partner of a speaker or attendee was in attendance*.[99] Relators' Counsel identified just six out of over 3,000 events where, allegedly, the non-medical spouse or partner of a speaker or attendee was present. But Relators do not provide any evidence as to how they determine these pairs were married, or that the spouse was non-medical.

---

96 Gilead 2016 Business Conduct Manual, Gilead_Purcell_00000330, p. 68.

97 Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 76. While the Gilead 2017 Business Conduct Manual includes the same description regarding repeat attendance as the 2016 Business Conduct Manual (*see* Gilead_Purcell_00000639, p. 67), a June 2017 email (Gilead_Purcell_00116569) indicates that the policy was adjusted as of July 2017.

98 Note that I have relied on whether a speaker previously spoke on a topic prior to attending an event on the same topic as a proxy for determining whether they were certified to speak on that topic. Further, I relied on the name matching approach that it appears Relators' Counsel used to identify individuals who allegedly spoke and then attended an event on the same topic; this methodology may categorize two different people with the same name as the same person. Indeed, four of the 8 remaining programs identify Mark Li as an attendee after speaking, but, as I describe above, Mark Li the speaker was a different person from Mark Li the attendee. Speaker Program Spend Reports.

99 Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 2.

4) *Programs at which three or fewer prescribers were in attendance*.[100] As I discuss in my Initial Report, Gilead's OLP speaker programs were not exclusively targeted at prescribers.[101] For example, community events educated high-risk communities on how HBV is transmitted, risk factors for infection, symptoms, disease progression, common false and stigmatizing information, testing, interpreting test results, what treatment entails (i.e., not specific to Gilead products), access to treatment, preventing future transmission, etc.[102] Given that these events are explicitly targeted at the community, one would have no expectation of having any prescribers, let alone four, in attendance. Relators' Counsel and Dr. Hay nevertheless include 42 community programs in this category of too-few prescribers in attendance. Similarly, as I discuss in my Initial Report, given the unique attributes of HBV, there is substantial value to educating non-prescribing HCPs on the risks of and treatments for HBV.[103] Furthermore, Relators' Counsel provide no information on how they identified attendees as prescribers versus non-prescribers.
5) *Programs at which at least one non-medical attendee was present*.[104] Based on Interrogatory Response Exhibit 5, which categorizes attendees based on whether they were "prescribers" or "non-prescribers," it appears Relators' Counsel and Dr. Hay include all events in this category where at least one "non-prescriber" (not

[100] Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 6.

[101] *See, e.g.*, Initial Report, Sections III.C and IV.A.2.

[102] Initial Report, ¶ 60.

[103] *See*, *e.g.*, Initial Report, ¶ 99.

[104] Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 5.

one "non-medical attendee") was present. As I discuss for Category (4), there are many events where one would expect non-prescribing (and even non-medical) attendees.

Moreover, from a physician's perspective, I do not believe that the presence of a non-prescriber would undermine the educational value of one of these events, and, based on Relators' Counsel's own categorization, nearly 99 percent of the events included in this "sham" category also had prescribers present.[105]

6) *Programs at which more than 25 percent of those in attendance were non-prescribers*.[106] Given the "sham" events identified immediately above, this category is duplicative of Category (5), as all events at which more than 25 percent of those in attendance were non-prescribers, by definition, must have had at least one non-prescriber present.

7) *Programs where one of the attendees had already attended at least two similar programs that calendar year.*[107] Based on my experience as a physician, there can be ample benefit to hearing the same information multiple times, especially if is delivered by different physicians with different experiences.

In addition, prior to 2016, Gilead's Business Conduct Manual did not have any restrictions on the number of times an attendee was permitted to attend its HBV speaker programs. 168 of the 317 events that Relators' Counsel identify in

[105] First Set of Interrogatory Responses, Exhibit 5.

[106] Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 4.

[107] Hay Corrected Report, ¶ 26. First Set of Interrogatory Responses, Exhibit 9.

this "sham" category occurred prior to 2016. In 2016, Gilead's Business Conduct Manual permitted attendees to "attend the same Program topic a maximum of three (3) times per calendar year."[108] Even using an overly inclusive name-matching methodology (which appears to be the approach Relators' Counsel took and will identify two people with the same name as one person), relying on this criteria for programs that occurred in 2016 reduces the number of events on this list from 35 to 11. Beginning in 2017, attendees were permitted to "attend the same Program topic a maximum of three (3) times per lifetime of the topic, and up to 10 Gilead Speaker Programs per calendar year, regardless of topic."[109] Additionally, Relators' Counsel and Dr. Hay appear to include Gilead employees as repeat attendees during the 2017 - 2019 period.[110] Relying on this criteria and removing Gilead employees for programs from July 2017 onward reduces the number of events on this list from 114 to 8. Taken together, these criteria reduce the number of programs on this list from 317 events to 19 events.[111]

---

[108] Gilead 2016 Business Conduct Manual, Gilead_Purcell_00000330, p. 68.

[109] Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 76. While the Gilead 2017 Business Conduct Manual includes the same description regarding repeat attendance as the 2016 Business Conduct Manual (*see* Gilead_Purcell_00000639, p. 67), a June 2017 email (Gilead_Purcell_00116569) indicates that the policy was adjusted as of July 2017, but events attended beginning in January 2017 were to be counted towards attendee totals.

[110] I identify Gilead Employees as individuals who are ever listed as "collaborators" in the "Role" field in the 2017 - 2019 Sign-in Data (IQV-Gilead-092879). I relied on the name matching approach that it appears Relators' Counsel used to identify alleged repeat attendees.

[111] I relied on the name matching approach that it appears Relators' Counsel used to identify alleged repeat attendees; this methodology will categorize two different people with the same name as the same person, which can result in over-identification of "repeat" attendance. For example, relying on name matching alone would identify event "INT-0012258" as having an attendee who had been to four events on the same topic, Wei Wang. But the Wei Wang in attendance at this event is a physician in CA, while a different Wei Wang from MA had previously attended an event on this topic, as well. Speaker Program Spend Reports. IQV-Gilead-137336, IQV-Gilead-092879 ("Sign-in Data").

8) *Programs at which the members of a so-called "pod" of attendees (a group of five or more who regularly attended programs together) were present.*[112] Relators' Counsel alleges that events with "pods" of attendees should be considered "sham." Based on my own experience, it is common for physicians in the same practice to attend events together, and, similarly, physicians who have similar specialties and reside in the same geographic area.

Irrespective of the fact that I would expect "pods" of physicians to attend the same events, Relators' Counsel identified events in this category that 1) had only a portion of the "pod" present (including 76 percent that had less than half of the "pod" present, and 44 percent that only had *one member* of the pod present); and 2) had many other attendees present. For example, 91 percent of the events with available attendee information had at least 4 attendees present in addition to those identified as "pod" members.[113]

Furthermore, there are events included in this list where the alleged "pod" member was not actually present at the event. For example, Exhibit 8 indicates that George Lin attended events "8017811" and "8019685," and that no other "pod" members were in attendance. But the AHM attendee spend and sign-in data indicate that even George Lin was not in attendance.[114] Based on the described "sham" criteria, it does not appear these events should be included on this list.

---

[112] Hay Corrected Report, ¶ 26, First Set of Interrogatory Responses, Exhibits 7 and 8.

[113] Note that 16 events included in this category do not appear in the Gilead HBV speaker program data and thus no additional attendance information is available. Relators' Counsel provides no additional information on when these events occurred or how they were identified.

[114] Sign-in Data. Speaker Program Spend Reports.

63. Exhibit 4 summarizes how each "sham" category contributes to overall damages, the impact of removing that category from the calculation when accounting for events that appear in multiple categories, and the objective event identification issues associated with each category.

Excerpt of Exhibit 4[115]

Dr. Hay's Alleged "Sham" Speaker Program Damages Summary
2013 - 2019

Dr Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Programs:	Total Claims:	Total Damages:	
	3,004	48,163	$44,913,418	
Relators' Description of "Sham" Event Category	**Unique Program Count[1]**	**Claims Associated with Category Programs**	**Damages Associated with Category Programs[1]**	**Objective Issues Associated with Event Identification**
Programs at which the average cost of a meal was over $65 per person	2,656	41,814	$38,773,095	Includes events where the meal spend was <$65 per person
Programs at which at least one non-medical attendee was present	2,176	35,232	$32,760,412	No information provided on how medical vs non-medical attendees identified
Programs at which more than 25% of those in attendance were non-prescribers	1,418	23,601	$22,200,026	No information provided on how medical vs non-medical attendees identified
Programs at which a speaker was in attendance after having served as a paid speaker	703	10,756	$9,539,986	Misidentification of different people as the same person; criteria do not align with BCM
Programs at which three or fewer prescribers were in attendance	538	4,779	$4,506,536	No information on how prescribers vs non-prescribers identified
Programs where one of the attendees had already attended at least two similar programs that calendar year	317	5,463	$5,059,912	Misidentification of different people as the same person; inclusion of Gilead personnel as repeat attendees; criteria do not align with BCM
Programs at which the members of a so-called "pod" of attendees (a group of five or more who regularly attended programs together) were present	94	3,070	$2,753,658	Inclusion of programs where no or very few "pod" members were in attendance
Programs at which a non-medical spouse or partner of a speaker or attendee was in attendance	5	52	$26,902	No information provided on how spouses were identified

[115] Programs may fall under multiple "sham" program categories. As a result, the sum of values in the "unique program count" column exceeds the "Total Programs" reported in the top row. Similarly, the impact of removing an individual event category may not reduce damages by the full amount reported in the "Damages Associated with Category Programs" field. I reserve the right to calculate alternatives damages estimations should the Court determine any particular combination of "sham" categories accurately identifies kickbacks to the paid speaker. Two programs included by Dr. Hay in his "sham" speaker program damages approach are not included in the Interrogatory Exhibits provided by Relators' Counsel. These two programs are not included in any categories above but are accounted for in Dr. Hay's overall damages total and the total unique program count. CMS Medicare Part D Prescription Drug Event Data; CMS Medicaid claims data; Tricare data; Hay Corrected Report and associated production materials; First Set of Interrogatory Responses.

64. Ultimately, based on the evidence provided in this case and my experience as a physician, I do not believe the categories Relators' Counsel rely on for identifying alleged "sham" events are actually indicators of whether an event had educational value, or that it was intended to induce the speaker to prescribe Viread® or Vemlidy®. Furthermore, neither Relators' Counsel nor Dr. Hay provide any clear methodology to identify events falling into these categories, and it is clear that events they identified do not always meet the described criteria. I find Dr. Hay's "sham" program damages calculation to be unsupported by the facts of this case and entirely unreliable in its execution.[116]

D. Dr. Hay does not provide or refer to any evidence indicating that advisory board programs were "sham" and fails to consider variation across advisory board programs

65. As I discuss extensively in my Initial Report, advisory boards are an exceedingly common tool both within and outside of the pharmaceutical industry.[117] My review of the materials associated with Gilead's advisory board programs supports that they served a legitimate business purpose and were aligned with the OIG guidelines around such events.[118]

66. Dr. Hay calculates alleged damages related to physician participation at certain advisory board programs, based on the premise that "Gilead also provided ad board incentives for prescribers"[119] and a "list of ad board participants at various conferences from 2013 - 2019."[120] Similar to the lack of a clear methodology and obvious errors in the speaker program

---

[116] I reserve the right to revise my analysis of these factors should Relators present additional evidence or explanation on these factors that the Court deems relevant to identifying these programs as "sham."

[117] Initial Report, Section IV.B.1.

[118] Initial Report, Section V.

[119] Hay Corrected Report, ¶ 32.

[120] Hay Corrected Report, ¶ 52.

"sham" categorizations, Relators' Counsel and Dr. Hay again fail to provide any information on how they identified unique, illegitimate events, or advisors participating in these events.

67. Dr. Hay provided a list of 25 advisory board programs and the advisors allegedly in attendance at each that he "received" from an undisclosed source.[121] The list assigns a single date to each program and includes a designation of the underlying product allegedly discussed. Without information on how the creator of this list identified these particular programs, I attempted to discern the methodology using the underlying Gilead advisory board payment data.[122] The list appears to combine several advisory board programs across different dates and locations based on general discussion topics. It then assigns a date to each group of programs based on the last program in the combined set. By manually assigning incorrect dates to certain programs, reliance on this list distorts the time-based nature of Dr. Hay's damages calculations, assigning alleged damages based on dates not pertinent to specific programs and advisors.

68. Furthermore, it is not always clear how the list combines advisory board programs or identifies advisors in attendance. For example, the list includes 22 advisors allegedly in attendance at a program titled "Women's Issues 2014" taking place on March 25, 2014.[123] The underlying Gilead payment data show only 21 advisors at the only program recorded on March 25, 2014.[124] The additional advisor in Dr. Hay's list, Stephen W. Ho, did not receive an advisory board honoraria payment on March 25, 2014, and appears to have received only one advisory board honoraria payment nearly a year earlier on, April 18, 2013. It is unclear why Dr. Ho is

---

121 Hay Corrected Report, ¶ 52 and associated production materials.

122 Advisory Board Spend Reports.

123 Hay Corrected Report and associated production materials.

124 Advisory Board Spend Reports.

included as attending this program despite no payment record in the underlying data. Similarly, for an event on June 1, 2019 entitled "NP/PA 2019," the list suggests Paula Cox-North and Meiting Liang were in attendance, despite no record of these advisors attending programs in June 2019, or any programs after 2017 for that matter.[125] Dr. Hay's inclusion of advisors who did not receive payments for the programs he alleges undermines the reliability of his calculations related to advisory board programs.

69. Similar to my conclusion related to Dr. Hay's "sham" speaker programs approach, I do not find (and Dr. Hay and Relators' Counsel do not provide) any evidence to suggest that the identified advisory board programs were illegitimate or that they resulted in improper Viread®/Vemlidy® prescribing.

E. Dr. Hay's damages calculations fail to address a number of other program-specific, physician-specific, and patient-specific factors

70. In the event that the Court were to find evidence that some honoraria payments to speakers and advisors were in fact kickbacks, I also consider a number of other shortcomings in Dr. Hay's damages calculation. First, Relators' Counsel and Dr. Hay fail to acknowledge important variations across speaker and advisory board programs, including whether they were community events, unbranded events, or in-office events. Second, there is no consideration of factors that influence a physician's decision to prescribe a particular medication, including whether the patient they are treating was initiated on a medication that was working well under the care of another physician. Finally, Dr. Hay's calculations fail to account for rebates provided to the government, and the cost related to alternative treatments that the government would have

[125] Hay Corrected Report and associated production materials. Advisory Board Spend Reports.

incurred had patients not been prescribed Viread® or Vemlidy®. I calculate the implications of adjusting for these failures below.

1. *Dr. Hay incorrectly includes community, unbranded, and in-office events in his damages calculations*

71. As I describe in my Initial Report, speaker and advisory board programs vary across a number of different attributes, including target audience, subject matter, and venue type.[126] Dr. Hay fails to acknowledge or consider how this type of variation speaks to whether or not an event was likely to be a "sham." As a result, Dr. Hay includes "damages" related to events targeted at the patient community, events that were not associated with Gilead's products (i.e., "unbranded" events), and in-office events that would have no draw to physicians other than to receive an education. It is unreasonable to consider events falling under any of these categories to be "sham" events.

72. Documents associated with Gilead's community programs demonstrate a tailored approach to educating communities at high risk of HBV. I provide various examples of these programs in my Initial Report.[127] All of these events were focused on general HBV education rather than a specific focus on Viread® or Vemlidy® (i.e., they were unbranded). Many of these events had hundreds of community members in attendance, and collaborations for screening helped diagnose attendees with HBV who may have otherwise gone untreated.[128] Relators' Counsel identified 48 community events as "sham."[129] These events bear no indicators of "sham" programs. Removing community programs from Dr. Hay's speaker program damages calculation

---

126 Initial Report, Section III.C, ¶ 90.

127 Initial Report, ¶ 60.

128 *See* Initial Report Exhibit 11 for community program attendance summary; *see, e.g.* Gilead_Purcell_00279891 for event with screened and diagnosed participants.

129 First Set of Interrogatory Responses. Speaker Program Spend Reports.

results in a decrease of $0.3 million, or 0.60 percent of Dr. Hay's total alleged 3-month damages.[130]

73. Gilead also held speaker programs targeted at HCPs that were unbranded, 919 of which Relators' Counsel identified as "sham."[131] Per Gilead's Business Conduct Manual, unbranded events rely on "[m]aterials that do not mention a product or include brand colors and logos and are intended to educate HCPs, patients, or the general community on particular disease states."[132] Under direction from Relators' Counsel, Dr. Hay "assume[s] that any unbranded program prior to October 31, 2016 could be attributed to Viread, and any unbranded program on or after November 1, 2016 could be attributed to Vemlidy."[133] This assumption does not align with the content of unbranded programs, and given that Viread® and Vemlidy® would not be the explicit focus of these events, they should not be included as "sham" programs. Removing unbranded programs (including the $0.3 million in damages associated with community programs) from Dr. Hay's speaker program damages calculation results in a decrease of $6.7 million, or 15.0 percent of Dr. Hay's total alleged 3-month damages.[134]

74. Additionally, Relators' Counsel and Dr. Hay allege that 303 events hosted in physicians' offices were "sham" programs.[135] Simultaneously, they include a category of "sham"

---

130 Note that this adjustment simply removes all community programs from the "sham" list. To the extent that a speaker spoke at another program that Relators' Counsel identified as a "sham," his or her prescriptions would still be included for 3-months following the remaining event(s).

131 First Set of Interrogatory Responses. Speaker Program Spend Reports.

132 *See, e.g.,* Gilead 2018 Business Conduct Manual, Gilead_Purcell_00000869, p. 26.

133 Hay Corrected Report, ¶ 56.

134 Note that this adjustment simply removes all unbranded (including all community programs, which are all unbranded) from the "sham" list. To the extent that a speaker spoke at another program that Relators' Counsel identified as a "sham," his or her prescriptions would still be included for 3-months following the remaining event(s).

135 First Set of Interrogatory Responses. Speaker Program Spend Reports.

programs based on whether the attendee meal spend was over $65, implying that high meal spend was required to attract attendees, and thus the event had no educational value. The presence of this "sham" category is fundamentally at odds with the suggestion that in-office programs were "sham"; physicians' offices are decidedly un-luxurious, and it is unfeasible that an attendee would be present for any reason besides education. Removing in-office programs from Dr. Hay's speaker program damages calculation results in a decrease of $2.2 million, or 5.0 percent of Dr. Hay's total alleged 3-month damages.[136]

75. Finally, Relators' Counsel and Dr. Hay include alleged 20 "sham" programs where the speakers did not receive any honoraria payments. [137] The inclusion of these programs makes no sense in light of the allegations in this case which claim that Gilead was running a "pay for play scheme;" [138] you cannot have a "pay for play" when no payment occurs. Removing programs where the speaker did not receive an honorarium payment from Dr. Hay's speaker program damages calculation results in a decrease of $0.03 million, or 0.1 percent of Dr. Hay's total alleged damages.[139] While these events do not have a substantial impact on damages, their inclusion demonstrates the extreme carelessness and unreliability of Dr. Hay's damages calculation.

---

[136] Note that this adjustment simply removes all in-office programs from the "sham" list. To the extent that a speaker spoke at another program that Relators' Counsel identified as a "sham" (including a community or unbranded program), his or her prescriptions would still be included for 3-months following the remaining event(s).

[137] First Set of Interrogatory Responses. Speaker Program Spend Reports.

[138] Fourth Amended Complaint at ¶ 2, *United States of America, et al., ex rel. Purcell and Groome v. Gilead Science, Inc.*, No. 17-cv-3523 (E.D. Pa. Sept. 30, 2020), ECF No. 117 (hereafter, "Complaint").

[139] Note that this adjustment simply removes all programs with $0 in honoraria payments from the "sham" list. To the extent that a speaker spoke at another program that Relators' Counsel identified as a "sham" (including a community, unbranded, or in-office program), his or her prescriptions would still be included for 3-months following the remaining event(s).

2. *Dr. Hay fails to account for the many factors that influence an HCP's decision to prescribe a particular drug*

76. Dr. Hay makes no effort to identify prescriptions that were "arising from and related to"[140] OLP payments. He simply assumes that all prescriptions written following a speaker program or advisory board were "arising from and related to" that payment. As I discuss extensively in my Initial Report, there are many factors that physicians rely on to make prescribing decisions, including clinical, patient, and physician considerations.[141] In order to isolate prescriptions "arising from and related to" OLP payments, which Dr. Hay states was his assignment,[142] he simply assumes that every single prescription for every single patient for three months following the receipt of a speaker or advisory board payment was a result of that payment.[143]

77. While certain considerations are unobservable from a data perspective, others can be easily identified. Specifically, when a patient initiates Viread® or Vemlidy® treatment under the care of a non-speaker/advisor or prior to any allegedly improper payment, it is unreasonable to think that, had that speaker/advisor not received an OLP payment, he or she would have *switched* the patient from a medication that was working to a different medication. Excluding prescriptions for patients who were initiated on Viread® or Vemlidy® by a non-speaker/advisor reduces Dr. Hay's speaker program damages by $5.1 million, or 11.3 percent of Dr. Hay's total

---

[140] Hay Corrected Report, ¶ 2.

[141] Initial Report, Section VI.A.

[142] Hay Corrected Report, ¶ 2.

[143] Note that Dr. Hay goes as far as assuming every single prescription for every single patient following a speaker or advisory program payment *in perpetuity* arose exclusively from that payment, but for the purposes of my analyses I only consider the three month sensitivity, as the presence of this sensitivity inherently suggests that there is a lack of evidence that Dr. Hay believes payments could have had a longer influence on prescribing. If the Court decides otherwise, I reserve the right to calculate damages adjustments under alternative scenarios.

alleged 3-month damages and his advisory board damages by $1.3 million, or 16.6 percent of Dr. Hay's total alleged 3-month damages. Excluding prescriptions for patients who were initiated on Viread® or Vemlidy® prior to a speaker or advisor's first allegedly improper payment reduces Dr. Hay's speaker program damages by $11.9 million, or 26.5 percent of Dr. Hay's total alleged 3-month damages and advisory board damages by $3.7 million, or 47.7 percent of Dr. Hay's total alleged 3-month damages.[144]

78. Exhibit 5 summarizes each of these damages adjustments. When taken together, these adjustments reduce Dr. Hay's speaker program damages by $21.2 million, or 47.1 percent of Dr. Hay's total alleged 3-month damages and advisory board damages by $4.7 million, or 60.1 percent of Dr. Hay's total alleged 3-month damages.

[144] Note that the patient-specific adjustment figures reported in this paragraph are completed separately from the program exclusions described in Section IV.E.1. That is, all events that Relators' Counsel identified as "sham" events are included in these calculations.

Excerpt of Exhibit 5[145]

Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Claims: 48,163	Total Damages: $44,913,418
Description of Adjustment	**Claims Associated with Adjustment**	**Damages Associated with Adjustment**
Exclude unbranded programs	7,540	$6,725,265
Exclude in-office programs	2,405	$2,236,533
Exclude community programs	304	$268,334
Exclude programs with zero total honoraria	29	$26,208
Exclude patients initiated on Viread or Vemlidy by non-speaker	5,476	$5,082,899
Exclude patients initiated on Viread or Vemlidy by speaker prior to any "sham" payments	13,766	$11,906,754
Cumulative impact of adjustments	**23,572**	**$21,165,087**
Remaining alleged speaker program damages	**24,591**	**$23,748,331**

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following Advisory Board Programs):	Total Claims: 8,384	Total Damages: $7,779,434
Exclude patients initiated on Viread or Vemlidy by non-speaker	1,367	$1,294,686
Exclude patients initiated on Viread or Vemlidy by speaker prior to any "sham" payments	4,093	$3,709,270
Cumulative impact of adjustments	**5,174**	**$4,676,443**
Remaining alleged advisory board program damages	**3,210**	**$3,102,990**

3. *Dr. Hay's damages calculations include a number of errors and conceptual omissions*

79. From an economic perspective, damages should be calculated as the difference between what the government paid and what it would have paid absent the alleged conduct. As

[145] Programs and claims may meet multiple adjustment criteria. The sum of values in the "claims associated with adjustment" and "damages associated with adjustment" columns thus exceed the total values reported in the cumulative row. Speaker Program Spend Reports; Advisory Board Spend Reports; CMS Medicare Part D Prescription Drug Event Data; CMS Medicaid claims data; Tricare data; Hay Corrected Report and associated production materials.

such, to accurately assess government loss, if any, it is not sufficient to accurately calculate Viread® and Vemlidy® reimbursements following the alleged improper conduct. It is also necessary to consider what the government would have paid in the absence of that conduct. As I discuss in my Initial Report, HBV is a chronically underdiagnosed condition and, if left untreated, can progress to much more dangerous (and costly) conditions.[146] If diagnosed patients had not been prescribed either Viread® or Vemlidy®, the government would have paid for an alternative therapy to treat these patients. A proper and accurate calculation of government loss is the difference between what the government paid for Viread® or Vemlidy® and what it would have paid for an alternative therapy.

80. For both Viread® and Vemlidy®, I consider other HBV antivirals as alternative therapies. I calculated the weighted average Medicare and Medicaid reimbursements per month of therapy during the 2013 - 2019 period for these alternative products and determined that government reimbursements would have been approximately 68 percent of what they were for Viread® and Vemlidy®.[147] Notably, from 2013 - 2014, the cost of Baraclude (the most common HBV antiviral treatment after Viread® during this time period) was more expensive than Viread®. In other words, during these years it would have been more costly for the government to pay for HBV treatment with Baraclude than it was to reimburse for Viread®.[148] Accounting for costs associated with alternative treatments reduces Dr. Hay's speaker program damages by

---

[146] Initial Report, Section III.A.

[147] The cost of alternative treatments is based on the paid amounts for other HBV antiviral medications. The costs are calculated annually and separately for each payor, normalized to a 30-day supply, and weighted by days-supply and non-Gilead HBV antiviral share (based on volume shares from the Symphony Health Data). The Tricare data do not include costs associated with non-Gilead HBV antiviral products and thus these costs are estimated based on the minimum Medicare or Medicaid (i.e., conservative) alternative cost in each year. To do this, I first calculate the Medicare and Medicaid alternative cost as a percentage of the combined cost of Viread® and Vemlidy®, respectively. Next, I take the minimum between these two percentages and multiply by the combined Tricare cost of Viread® and Vemlidy® in each year.

[148] Production materials related to Exhibit 6.

$30.6 million, or 68.1 percent of Dr. Hay's total alleged 3-month damages and advisory board damages by $6.1 million, or 78.1 percent of Dr. Hay's total alleged 3-month damages.

81. Additionally, Dr. Hay fails to account for (or acknowledge) rebates that Gilead provided to the government related to reimbursements for Viread® and Vemlidy®, resulting in an overestimate of damages. Medicaid statutorily requires drug manufacturers to offer rebates to be eligible for reimbursement under the program.[149] Medicaid classified Viread® as a "single source" drug prior to 2019 and some formulations as an "Innovator multiple source" beginning in 2019, while Vemlidy® has been and remains categorized as a "single source" drug;[150] both classifications are associated with a ***minimum*** 23.1 percent rebate off of the Average Manufacturer Price.[151] Medicaid's rebate calculations also include an inflationary component that increases rebates when drug prices increase faster than inflation—when combined with the aforementioned minimum, this is referred to as the Unit Rebate Amount ("URA").[152] Rebate data produced by Gilead provides data on the total URA that applied to Medicaid payments for Viread® and Vemlidy®.[153] Based on Gilead's rebate data, Gilead provided Medicaid with rebates ranging from 60 to 84 percent annually for Viread® and from 32 to 33 percent for

---

149 CMS Medicaid Drug Rebate Program Data, available at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-data/index.html.

150 CMS Medicaid Drug Rebate Program Data.

151 Medicaid, "Unit Rebate Amount Information," available at https://www medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index html. *See also,* Social Security Act, Section 1927 c.1 B.i.VI, available at https://www.ssa.gov/OP_Home/ssact/title19/1927 htm. Notably, on its 2017 10-k Gilead states that "state Medicaid programs could request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate." Gilead Sciences, Inc., Form 10-K Annual Report, 2017, available at https://www.annualreports.com/HostedData/AnnualReportArchive/g/NASDAQ_GILD_2017.pdf.

152 Dolan, Rachel, "Understanding the Medicaid Prescription Drug Rebate Program," *KFF*, November 12, 2019, available at https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/.

153 Gilead_Purcell_00341126 ("Gilead Medicaid Rebate Data").

Vemlidy®; accounting for these rebates reduces Dr. Hay's speaker program damages calculation by $0.5 million, or 1.0 percent of Dr. Hay's 3-month damages and advisory board damages by $0.3 million, or 4.0 percent of Dr. Hay's total alleged 3-month damages.[154]

82. Finally, Dr. Hay neglects to account for the fact that Viread® is indicated for the treatment of HIV in addition to the treatment of HBV.[155] The data request for Medicare, Medicaid, and Tricare data did not limit to patients being treated for HBV, and Dr. Hay made no attempt to exclude Viread® use associated with HIV treatment, despite the fact that the allegations in this case are focused on HBV OLP programs.[156]

83. Exhibit 6 summarizes each of these adjustments, as well as the cumulative impact when combined with the above adjustments.[157] When taken together, these adjustments reduce Dr. Hay's speaker program damages by $34.7 million, or 77.2 percent of Dr. Hay's total alleged 3-month damages and advisory board damages by $6.7 million, or 86.5 percent of Dr. Hay's total alleged 3-month damages.

---

[154] The Medicaid rebate percentage is calculated as the product of the unit rebate amount ("Line Payment Amount" divided by "Paid Units") from the Gilead Medicaid Rebate Data and total "Days Supply" in the Medicaid Claims Data, divided by the total amount paid ("MDCD PD AMT") in the Medicaid Claims Data. To account for differences in days supply, I only included tablet formulations of Viread® and Vemlidy® in both the rebate data and Medicaid claims data, and considered a 30 day supply to be the equivalent of 30 units.

[155] "U.S. Food and Drug Administration Approves Viread® for Chronic Hepatitis B in Adults," *Gilead*, August 11, 2008, available at https://tinyurl.com/zh3tv48n.

[156] CMS Data Use Agreement (Form CMS-R-0235) (Sept. 9, 2020), pp. 15-16. Complaint, ¶ 1.

[157] The cumulative adjustment does not include the discussed rebate adjustment, as I am aware of no comparable rebate data available for non-Gilead HBV products. Annual results for the "Remaining alleged "sham" speaker program damages" and "Remaining alleged advisory board program damages" can be found in Appendices 2 and 3, respectively.

Excerpt of Exhibit 6[158]

Cumulative Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Claims: 48,163	Total Damages: $44,913,418
Description of Adjustment	**Claims Associated with Adjustment**	**Damages Associated with Adjustment**
Adjustments associated with incorrectly included claims (per Exhibit 5)	23,572	$21,165,087
Account for cost of alternative treatments[2][3]	*N/A*	$30,624,412
Cumulative impact of adjustments	**23,572**	**$34,650,796**
Remaining alleged "sham" speaker program damages	**24,591**	**$10,262,622**
Account for rebates paid to Medicaid[4]	*N/A*	$459,386

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following Advisory Board Programs):	Total Claims: 8,384	Total Damages: $7,779,434
Adjustments associated with incorrectly included claims (per Exhibit 5)	5,174	$4,676,443
Account for cost of alternative treatments[2][3]	*N/A*	$6,074,367
Cumulative impact of adjustments	**5,174**	**$6,732,891**
Remaining alleged advisory board program damages	**3,210**	**$1,046,542**
Account for rebates paid to Medicaid[4]	*N/A*	$295,681

V. DR. BIAETT'S CONCLUSIONS ARE ANECDOTE-DRIVEN AND ARBITRARY

84. Dr. Biaett's report is based on a handful of cherry-picked examples and arbitrary thresholds. Dr. Biaett does not perform any disciplined analysis of the specific Gilead events and does not provide any evidence aside from his own personal opinion, a random and simplistic review of restaurant menus, and promotional quotes about the restaurants from the restaurants' own websites to support the conclusions that meals provided during Gilead's speaker programs were not "modest" and that Gilead's speaker programs took place in venues that were inappropriate and not conducive to educational seminars. Dr. Biaett does not perform any

benchmarking or methodological assessment to justify the arbitrary $65 limit he claims would allow for a "modest meal."[159]

85. The examples Dr. Biaett describes are entirely based on Polaris monitoring reports, and he has conducted no comprehensive analysis of whether or not such events were reflective of the thousands of events that were held during the at-issue time period. Dr. Biaett's report highlights a handful of cherry-picked examples, leaving out a large number of meetings in the reports in which the monitors included only positive or neutral summary information. For example, in one program which Dr. Biaett left out of his report, the monitor stated that it was a "very normal and 'as-expected' program. Room was perfect […] Dr. Nguygen was a very good speaker, he took his time explaining slides, added personal touches and was very passionate about the disease and product."[160] The monitor further commented on the speaker's presentation

---

[158] Programs and claims may meet multiple adjustment criteria. The sum of values in the "claims associated with adjustment" and "damages associated with adjustment" columns thus exceed the total values reported in the cumulative row. The cost of alternative treatments is based on the paid amounts for other HBV antiviral medications. The costs are calculated annually and separately for each payor, normalized to a 30-day supply, and weighted by days-supply and non-Gilead HBV antiviral share (based on volume shares from the Symphony Health Data). The Tricare data do not include costs associated with non-Gilead HBV antiviral products and thus these costs are estimated based on the minimum Medicare or Medicaid (i.e., conservative) alternative cost in each year. To do this, I first calculate the Medicare and Medicaid alternative cost as a percentage of the combined cost of Viread® and Vemlidy®, respectively. Next, I take the minimum between these two percentages and multiply by the combined Tricare cost of Viread® and Vemlidy® in each year. Alternative HBV treatments include Baraclude and its generic formulation, Epivir HBV and its generic formulation, Hepsera® and its generic formulation, Tyzeka, and the generic formulation of Viread®. The Medicaid rebate percentage is calculated as the product of the weighted average unit rebate amount (total "Line Payment Amount" divided by total "Paid Units") from the Gilead Medicaid Rebate Data and total "Days Supply" in the Medicaid Claims Data, divided by the total amount paid ("MDCD PD AMT") in the Medicaid Claims Data by year and drug. To account for differences between days supply and units, I only included tablet formulations of Viread® and Vemlidy® in both the rebate data and Medicaid claims data, and considered a 30-day supply to be the equivalent of 30 units. Rebates are not accounted for in the cumulative adjustment shown here. Speaker Program Spend Reports; Advisory Board Spend Reports; CMS Medicare Part D Prescription Drug Event Data; CMS Medicaid claims data; Tricare data; Hay Corrected Report and associated production materials; Symphony Health Data (accessed on March 18, 2021); Gilead Medicaid Rebate Data; IBM Micromedex Red Book Online.

[159] Biaett Report, Summary of Opinions, ¶ 4.

[160] Gilead_Purcell_00006183, meeting ID 8040940.

of specific slides, for example saying that on one slide the "speaker made sure to emphasize how we [sic] reduces dosing with his patients," on another slide "gave some additional scenarios to provide contrast to the audience around risks," and on another slide "ma[de] sure to answer the discussion questions and focused on ultrasounds and continuing treatment."[161] In another program, the monitor concluded that "[o]verall, the speaker was thorough in presenting the materials and good at making sure to pause frequently in order to make sure that any audience questions would be covered effectively. He also made sure to focus in detail on all key clinical studies and the associated data as well as on the general disease dmeographics [sic] which were used to set the context of the discussion."[162] In yet another program, the monitor concluded that it was a "[v]ery normal, straightforward program" and that the speaker "was very experienced in this space and has been speaking about Viread[®] for about 6 years. He wove a significant amount of personal experience and patient treatments into the overall presentation. He tailored the examples to ones that would be relevant for the PharmDs in the room and had a good command of the audience."[163]

86. In addition to only choosing a handful of unrepresentative events to highlight in his report, Dr. Biaett left out information for the events he did choose to highlight. For example, Dr. Biaett stated that a Gilead speaker program on August 22, 2016 "took place in the corner of the main dining room with other patrons…"[164] However, in the summary assessment the monitor provided further context on this, stating that "[t]he program took place in the main dining room

[161] Gilead_Purcell_00006183, meeting ID 8040940.

[162] Gilead_Purcell_00006183, meeting ID 8041147.

[163] Gilead_Purcell_00006183, meeting ID 8042965.

[164] Biaett Report, Assessment and Opinions, ¶ 12.

with other patrons, however, the few tables were located in the corner of the restaurant and not completely surrounded by other people."[165] The monitor also concluded "[i]t was overall a fair program" and "[t]he speaker did a good job in presenting and leading the discussion," going "over all of the suggested discussion questions thoroughly…"[166]

87. Dr. Biaett highlighted another meeting in his report in which "the venue was very noisy making it very difficult to hear the speaker."[167] Dr. Biaett left out that despite this, the monitor concluded that "there was a lot of good discussion among the attendees with the speaker throughout the program."[168]

88. Dr. Biaett describes his assignment as assessing whether or not the meal value was "modest" as that term is used in the PhRMA Code, however he devotes a large portion of his report to a simplistic assessment of venue descriptions contained on the restaurants' websites, which he describes as being "experiential and incentivizing in nature and designed for entertainment, as opposed to education."[169] These restaurant descriptions do not provide any meaningful information to address the question of whether the meal value was "modest." I am unaware of anyone having ever interpreted the PhRMA Code for that term (or any other piece of the PhRMA Code) by looking at restaurants' self-serving descriptions on their websites. In fact, Massachusetts' Public Health Counsel defines an acceptable meal expense standard, or a "modest meal," as "similar to what a healthcare practitioner might purchase when dining at his or

[165] Gilead_Purcell_00006184, meeting ID 8052657.

[166] Gilead_Purcell_00006184, meeting ID 8052657.

[167] Biaett Report, Assessment and Opinions, ¶ 11.

[168] Gilead_Purcell_00006184, meeting ID 8053719.

[169] Biaett Report, Assessment and Opinions, ¶ 15.

her own expense."[170] Furthermore, just because a restaurant describes their venue with the goal of attracting customers does not mean they cannot also provide a space conducive to an educational meeting, even if this is not their main line of business. In fact, some of these websites specifically mention their ability to host private events such as seminars and conferences, which is information Dr. Biaett omits from his table.[171] Indeed, relying on the general descriptions provided on restaurant websites ignores the fact that speaker programs were often held in private rooms.[172]

89. Dr. Biaett states that "more moderately priced restaurants," such as Outback Steakhouse or the Bonefish Grill, would be appropriate venues for a speaker program. However, their websites provide similar descriptions to venues included in Dr. Biaett's table. Outback Steakhouse describes their restaurants as "delivering a warm, welcoming environment," whose "casual atmosphere couldn't be more transporting" and whose employees "[take] food seriously, without forgetting any of the fun, knowing that nothing stands in the way of making you happy."[173] The Bonefish Grill offers a similar description of their restaurant, which has "personalized service that allows you to enjoy a delicious meal in a comfortable, vibrant atmosphere."[174]

---

[170] The Massachusetts Public Health Council has declined to implement a cap on the meal spending amount because "a specific dollar cap is a simplistic approach to a complex regulatory provision." *See,* Kannensohn, Kimberly J., et al., "United States: Massachusetts Public Health Council Approves 'Modest Meals' From Pharmaceutical And Medical Device Manufacturers To Healthcare Providers," *mondaq,* December 5, 2012, available at https://www.mondaq.com/unitedstates/healthcare/209942/massachusetts-public-health-council-approves-modest-meals-from-pharmaceutical-and-medical-device-manufacturers-to-healthcare-providers.

[171] *See, e.g.,* "Corporate Events," *Ruth's Chris Steakhouse,* available at https://www ruthschris.com/private-events/#corporate-events.

[172] See, e.g., Gilead_Purcell_00006184 (meeting codes 8053941, 8052983); Gilead_Purcell_00006183 (meeting codes 8040117, 8040056, 8041147, 8041574, 8042965, 8040475, 8040940).

[173] "All About Outback Steakhouse," *Outback Steakhouse,* available at https://www.outback.com/about-us.

[174] "The Experience," *Bonefish Grill,* available at https://www.bonefishgrill.com/about/the-experience.

90. By Dr. Biaett's standards, one would think that any positive description of a venue suggests that it is not modest. The following definition would meet that criteria: "making your mealtime experience all about you" during an "Experience of the Future."[175] However, this is how McDonald's describes its restaurants, which certainly would not be considered immodest. These venue descriptions are part of the restaurants' marketing and promotion efforts, aimed at making the restaurant appear desirable to potential customers. Dr. Biaett's meaningless review of these restaurant descriptions is in no way relevant to the specific events that took place during Gilead's Viread® and Vemlidy® speaker programs.

91. Dr. Biaett's baseless conclusion that $65 is an appropriate meal spend limit, but $125 is not, ignores the literature on the ethics of professional speaker programs, which cites a meal spend limit of $125 as an example of dinner service-related guidelines.[176] A 2017 survey of pharmaceutical meeting managers reported an average meal cap of $125 for dinner.[177] [redacted], and that payments to physicians were for providing legitimate medical education services.[178]

92. The only support Dr. Biaett provides for his $65 limit is a menu from Ruth's Chris Steakhouse. However, this menu price does not include tax, tip, parking, or the

---

175 "Creating the Restaurant Experience of the Future," *McDonalds,* available at https://corporate mcdonalds.com/corpmcd/en-us/our-stories/article/ourstories.future_restaurants.html.

176 Essi, David F., "Mixing Dinner and Drugs—Is It Ethically Contraindicated?" *American Medical Association Journal of Ethics*, August 2015, Vol. 17(8), pp. 787-795, at p. 788.

177 Pelletier, Sue, "Take a Sneak Peek at Pharma Planner Meal Cap Survey Results," *MeetingsNet*, January 18, 2017, available at https://www meetingsnet.com/pharmaceutical-meetings/take-sneak-peek-pharma-planner-meal-cap-survey-results.

178 Transcript from Deposition of Kimberly Groome, April 10, 2021, pp. 338:24-339:13, 348:6-11.

administration charge,[179] which brings the actual price of the meal to nearly $95.[180] Additionally, this menu price does not include alcoholic beverages, so if a speaker program offered attendees a glass of wine or a beer with their meal, the menu price would increase by approximately $11.71, for a total of nearly $107.[181] In my Initial Report, I found that the average total in-kind payments to speaker event attendees was only $97. Removing tax, tip, administration charge, and parking from this amount leads to a subtotal of $67, just ***two dollars*** higher than Dr. Biaett's proposed $65 cap.[182]

93. Dr. Biaett also appears to contradict himself by suggesting the $65 is modest as it includes a choice of filet, which Dr. Biaett refers to as part of an "expensive and non-modest meal."[183] Furthermore, Dr. Biaett's $65 cap seems to suggest that a venue is modest and appropriate if the per person cost is $65 or less. However, had Dr. Biaett analyzed the data as part of his analysis, he would have observed that there are many venues in which multiple different Gilead HBV speaker programs have been held where some events cost more than $65 per person and others cost less than $65 per person, *even though they take place at the same*

---

179 Gilead's Business Conduct Manual states that the $125 per person limit includes "food, drink, tax, parking (if reimbursed), and gratuities." *See* Gilead 2017 Business Conduct Manual, Gilead_Purcell_00000639, p. 34.

180 To calculate the after-tax total, I added together 7.12% for tax (the average sales tax rate in the US), 20% for tip, and 3% administration charge for a total of 30.12%. I multiplied 30.12% by the pre-tax total, $65, to get an additional cost of $19.58 and added on an additional $10 for parking. Added together, this amounts to $94.58. *See* Waggoner, John, "States With Highest and Lowest Sales Tax Rates," *AARP,* October 21, 2020, available at https://www.aarp.org/money/taxes/info-2020/state-sales-tax-rates.html; IQV-Gilead-015345 (receipt showing 20% gratuity); IQV-Gilead-017727 (Food & Beverage Agreement listing 20% gratuity).

181 Ruth's Chris happy hour menu lists $9 for a glass of wine. (*See* "Happy Hour," *Ruth's Chris Steakhouse*, available at https://www.ruthschris.com/menu/happy-hour/.) Adding tax, tip, and admin fee, brings the total to $11.72. This is consistent with the Food & Beverage agreement which specifies $9 per glass of wine or beer (*See* IQV-Gilead-017727).

182 Jena Initial Report, ¶ 89. To calculate the subtotal, I subtracted $10 for parking from the total amount, $97, and then divided by 130.12% (which includes the 30.12% total for tax, tip, and administration charge describe above in footnote 180), which results in a subtotal of $66.86.

183 Biaett Report, ¶¶ 3, 19.

venue. For example, several venues included in Dr. Biaett's report demonstrate this point: at Le Papillon, an event in 2013 cost $118 per person while another event the following year cost $60 per person; at Grand Garden, an event in 2014 cost $56 per person, while an event in 2016 cost $93; and at Koi Palace, an event in 2013 cost $120 per person, while one in 2017 cost $57 per person.[184] There are numerous other examples that make the same point: Dr. Biaett's $65 per person cap is an arbitrary threshold that is not based on any meaningful analysis of the data relevant to this case.

Anupam B. Jena, M.D., Ph.D.

May 26, 2021

[184] Speaker Program Spend Reports, program IDs 8022782, 8026145, 8031976, 8055641, 8018681, and INT-0001126.

APPENDIX C - REBUTTAL MATERIALS RELIED UPON

Court Documents

Fourth Amended Complaint, *United States of America, et al., ex rel. Purcell and Groome v. Gilead Science, Inc.*, No. 17-cv-3523 (E.D. Pa. Sept. 30, 2020), ECF No. 117

Plaintiff-Relators' Objections and Supplemental Response to Interrogatories 2,5,9, and 10 of Defendant's First set of Interrogatories, May 12, 2021

Depositions

Transcript from Deposition of Kimberly Groome, April 10, 2021

Bates Stamped Documents

Gilead_Purcell_00000330
Gilead_Purcell_00000486
Gilead_Purcell_00000639
Gilead_Purcell_00000869
Gilead_Purcell_00006183
Gilead_Purcell_00006184
Gilead_Purcell_00006322
Gilead_Purcell_00046904
Gilead_Purcell_00058651
Gilead_Purcell_00075800
Gilead_Purcell_00098375
Gilead_Purcell_00109300
Gilead_Purcell_00109542
Gilead_Purcell_00109677
Gilead_Purcell_00109731
Gilead_Purcell_00114455
Gilead_Purcell_00114779
Gilead_Purcell_00116569
Gilead_Purcell_00134580
Gilead_Purcell_00134582
Gilead_Purcell_00137107
Gilead_Purcell_00216563
Gilead_Purcell_00216770
Gilead_Purcell_00216771
Gilead_Purcell_00216772
Gilead_Purcell_00216774
Gilead_Purcell_00224639
Gilead_Purcell_00224964
Gilead_Purcell_00278464
Gilead_Purcell_00279007
Gilead_Purcell_00279891
Gilead_Purcell_00283133
Gilead_Purcell_00308509
Gilead_Purcell_00311268
Gilead_Purcell_00311272
Gilead_Purcell_00324518
Gilead_Purcell_00327015
Gilead_Purcell_00327017
Gilead_Purcell_00327018
Gilead_Purcell_00340769
Gilead_Purcell_00341126
IQV-Gilead-015345
IQV-Gilead-017727
IQV-Gilead-092879
IQV-Gilead-137336
PPI0010-034

Expert Reports

Expert Report of Vernon L. Biaett, May 3, 2021

Expert Report of Joel Hay (Corrected), May 9, 2021 and associated production materials

Expert Report of Anupam B. Jena, May 3, 2021

Expert Report of Professor Genevieve P. Kanter, May 3, 2021

Expert Report of Dr. Graham McMahon, May 3, 2021

Data

CMS Medicaid Claims Data

CMS Medicaid Drug Rebate Program Data, available at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-data/index.html

CMS Medicare Part D Prescription Drug Event Data

CMS Data Use Agreement (Form CMS-R-0235) (Sept. 9, 2020)

IBM Micromedex Red Book Online, available at https://www.micromedexsolutions.com/micromedex2/librarian/

Open Payments Data, Mark Li (Wheaton, MD), available at https://openpaymentsdata.cms.gov/physician/828693

Open Payment Data, Mark Li (Hacienda Heights, CA), available at https://openpaymentsdata.cms.gov/physician/106265

Tricare Data

Symphony Health Solutions IDV® pharmaceutical data. Retrieved from Bloomberg Professional database on March 18, 2021

Academic Books and Articles

Agha, Leila and Dan Zelter, "Drug Diffusion Through Peer Networks: The Influence of Industry Payments," *NBER Working Paper 26338,* December 2020

Avorn, Jerry, et al., "Scientific versus Commercial Sources of Influence on the Prescribing Behavior of Physicians," *The American Journal of Medicine,* July 1982, Vol.73(1), pp. 4-8

Bandari, Jathin et al., "The lack of a relationship between physician payments from drug manufacturers and Medicare claims for abiraterone and enzalutamide," *Cancer*, 2017, Vol.123(22), pp. 4356-4362

Brunt, Christopher Scott, "Physician Characteristics, Industry Transfers, and Pharmaceutical Prescribing: Empirical Evidence from Medicare and the Physician Payment Sunshine Act," *Health Services Research,* 2019, Vol.54(3), pp. 636-649

Carey, Colleen, et al., "Drug Firms' Payments and Physicians' Prescribing Behavior in Medicare Part D," *Journal of Public Economics,* 2021, Vol.197, pp. 1-14

DeJong, Colette et al., "Pharmaceutical Industry-Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries," *Jama Internal Medicine,* 2016, Vol.176(8), pp. 1114-1122

Essi, David F., "Mixing Dinner and Drugs—Is It Ethically Contraindicated?" *American Medical Association Journal of Ethics*, August 2015, Vol. 17(8), pp. 787-795

Fickweiler, Freek, et al., "Interactions between physicians and the pharmaceutical industry generally and sales representatives specifically and their association with physicians' attitudes and prescribing habits: a systematic review," *BMJ Open,* 2017, Vol. 7(9), pp. 1-12

Fleischman, William et al., "Association of Pharmaceutical Manufacturer Payments to Physicians and Prescribing Dosages of Opioids," *Journal of General Internal Medicine,* 2019, Vol.34(7), pp. 1074-1076

Heumann, Christian et al., "Introduction to Statistics and Data Analysis," *Springer*, 2016.

Larkin, Ian et al., "Association Between Academia Medical Center Pharmaceutical Detailing Policies and Physician Prescribing," *JAMA,* 2017, Vol.317(17), pp. 1785-1795 and supplementary online content

Mitchell, Aaron P. et al., "Are Financial Payments From the Pharmaceutical Industry Associated With Physician Prescribing?" *Annals of Internal Medicine,* 2021, Vol.174(3), pp. 353-361

Orlowski, James P. and Leon Wateska, "The Effects of Pharmaceutical Firms Enticements on Physician Prescribing Patterns," *Chest,* 1992, Vol.102(1), pp. 270-273

Parker-Lue, Sara, "The Impact of Reducing Pharmaceutical Industry Payments on Physician Prescribing," *Health Economics*, 2020, Vol.29(3), pp. 382-390

Phillips, Jack J., "Return on Investment in Training and Performance Improvement Programs," *Routledge*, Second Edition, 2003

Springarn, Roger W., et al., "When Pharmaceutical Manufacturers' Employees Present Grand Rounds, What Do Residents Remember," *Academic Medicine,* January 1996, Vol.71(1), pp. 86-88

Steinman, Michael A., et al., "Of Principles and Pens: Attitudes and Practices of Medicine Housestaff toward Pharmaceutical Industry Promotions," *American Journal of Medicine,* 2001, Vol.110(7), pp. 551-557

Taylor, Richard, EdD, RDCS, "Interpretation of the Correlation Coefficient: A Basic Review," *Journal of Diagnostic Medical Sonography*, January/February 1990, Vol. 6, pp. 35-39

Wooldridge, Jeffrey M., "Introductory Econometrics A Modern Approach," *South-Western Cengage Learning,* 2012, Fifth Edition

Yeh, James S. et al., "Association of Industry Payments to Physicians With the Prescribing of Brand-name Statins in Massachusetts," *JAMA Internal Medicine,* June 2016, Vol.176(6), pp. 763-768

Publicly Available Sources

"All About Outback Steakhouse," *Outback Steakhouse,* available at https://www.outback.com/about-us

"Approved Drugs for Adults," *Hepatitis B Foundation*, available at https://www.hepb.org/treatment-and-management/treatment/approved-drugs-for-adults/

"Code on Interactions with Healthcare Professionals," *PhRMA*, July 2008, available at https://tinyurl.com/zu4cfurw

"Common Inclusion/Exclusion Criteria," *The University of Melbourne,* April 29, 2021, available at https://unimelb.libguides.com/c.php?g=492361&p=3368110

"Corporate Events," *Ruth's Chris Steakhouse,* available at https://www.ruthschris.com/private-events/#corporate-events

"Creating the Restaurant Experience of the Future," *McDonalds,* available at https://corporate.mcdonalds.com/corpmcd/en-us/our-stories/article/ourstories.future_restaurants.html

"False Claims Code," 31 U.S.C. § 3729(a)(1), available at https://www.govinfo.gov/content/pkg/USCODE-2011-title31/pdf/USCODE-2011-title31-subtitleIII-chap37-subchapIII-sec3729.pdf

"Happy Hour," *Ruth's Chris Steakhouse*, available at https://www.ruthschris.com/menu/happy-hour/

"The Experience," *Bonefish Grill,* available at https://www.bonefishgrill.com/about/the-experience

"U.S. Food and Drug Administration Approves Viread® for Chronic Hepatitis B in Adults," *Gilead*, August 11, 2008, available at https://tinyurl.com/zh3tv48n

"What is Return on Investment (ROI)," *Corporate Finance Institute*, available at https://corporatefinanceinstitute.com/resources/knowledge/finance/what-is-return-on-investment-roi/

Dolan, Rachel, "Understanding the Medicaid Prescription Drug Rebate Program," *KFF*, November 12, 2019, available at https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/

Duke, Elizabeth, "OIG Compliance Program Guidance for Pharmaceutical Manufacturers," Department of Health and Human Services: Office of Inspector General, Federal Register, Vol. 68, No. 86, May 5, 2003, pp. 23731-23743

Gilead Sciences, Inc., Form 10-K Annual Report, 2017, available at https://www.annualreports.com/HostedData/AnnualReportArchive/g/NASDAQ_GILD_2017.pdf

Homer, Patrick, et al., "A Revolution in Physician Targeting," *SAS,* 2009, available at https://alfresco-static-files.s3.amazonaws.com/alfresco_images/pharma/2014/08/21/1cafa74e-5214-4d7a-ab18-08f860a37491/article-612371.pdf

Kannensohn, Kimberly J., et al., "United States: Massachusetts Public Health Council Approves 'Modest Meals' From Pharmaceutical And Medical Device Manufacturers To Healthcare Providers," *mondaq,* December 5, 2012, available at https://www.mondaq.com/unitedstates/healthcare/209942/massachusetts-public-health-council-approves-modest-meals-from-pharmaceutical-and-medical-device-manufacturers-to-healthcare-providers

Medicaid, "Unit Rebate Amount Information," available at https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/unit-rebate-amount-calculation/index.html

Pelletier, Sue, "Take a Sneak Peek at Pharma Planner Meal Cap Survey Results," *MeetingsNet*, January 18, 2017, available at https://www.meetingsnet.com/pharmaceutical-meetings/take-sneak-peek-pharma-planner-meal-cap-survey-results

Social Security Act, Section 1927 c.1 B.i.VI, available at https://www.ssa.gov/OP_Home/ssact/title19/1927.htm

Waggoner, John, "States With Highest and Lowest Sales Tax Rates," *AARP,* October 21, 2020, available at https://www.aarp.org/money/taxes/info-2020/state-sales-tax-rates.html

Exhibit 1
Viread/Vemlidy Honoraria Payments and Prescribing of Non-Gilead HBV Antivirals Among Speakers

Prescription Counts of Non-Gilead HBV Antivirals by Year			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	64.0846	18.3419	0.0005
Viread Honoraria	0.0030	0.0003	<.0001
Year	-5.4384	5.3682	0.3113

Prescription Counts of Non-Gilead HBV Antivirals by Year			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	73.7308	22.4330	0.0011
Vemlidy Honoraria	0.0110	0.0009	<.0001
Year	-11.3112	5.9947	0.0596

All Time Prescription Counts of Non-Gilead HBV Antivirals			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	227.7615	80.0587	0.0048
Viread Honoraria	0.0031	0.0006	<.0001

All Time Prescription Counts of Non-Gilead HBV Antivirals			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	143.1715	104.0837	0.1708
Vemlidy Honoraria	0.0115	0.0017	<.0001

Notes:

[1] Non-Gilead HBV antiviral prescribing is measured using the Managed Care Report prescription data from 2013 Q2-2017 and is compared to Viread/Vemlidy honoraria payments over the same time period.

[2] Regressions with Viread (Vemlidy) honoraria include speakers who ever received Viread (Vemlidy) honoraria payments during 2013-19 based on Dr. Hay's identification.

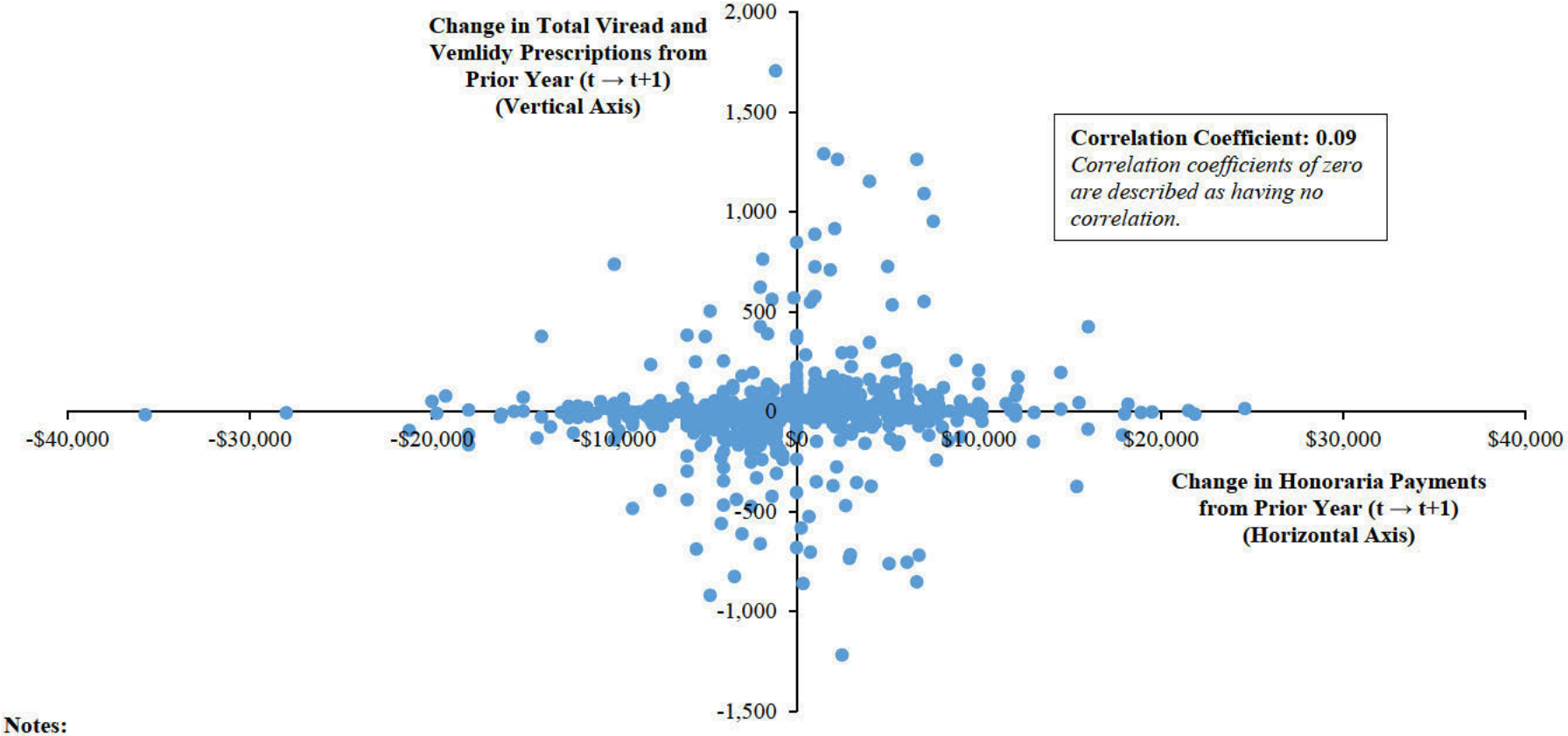
Sources:

[1] Gilead_Purcell_00046904, 00058651, 00075800, 00109300, 00109542, 00109677, 00109731, 00114455, 00114779, 00137107, 00216770, 00216771, 00216772, 00216774, 00224964, 00279007, 00283133 ("Managed Care Report Data").

[2] Corrected Expert Report of Joel W. Hay, PhD, May 9, 2021 and associated production materials.

[3] IBM Micromedex Red Book Online, available at https://www.micromedexsolutions.com/micromedex2/librarian/.

Exhibit 2
Annual Change in Gilead HBV Speaker Program Honoraria Payments and Medicare, Medicaid, and Tricare Viread and Vemlidy Prescriptions 2013 – 2019



Notes:
[1] This analysis is limited to HCPs that received honoraria payments.
[2] This analysis excludes years where both the change in total honoraria and total prescriptions from the prior year are zero.
[3] Honoraria payments include payments from speaker events.

Sources:
[1] CMS Medicare Part D Prescription Drug Event Data.
[2] CMS Medicaid claims data.
[3] Tricare data.
[4] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.

Exhibit 3
Viread and Vemlidy Regressions with Fixed Effects and Lagged Honoraria Payments

Viread by Year

Prescription Counts			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	36.1215	18.3591	0.0502
Lagged Honoraria Payments	0.0019	0.0024	0.4429
Year Indicators			
2015	20.4612	4.6399	<.0001
2016	149.2117	19.2098	<.0001
2017	107.4488	15.8281	<.0001

Vemlidy by Year

Prescription Counts			
Variable	**Parameter Estimate**	**Standard Error**	**p-value**
Intercept	111.9960	11.3561	<.0001
Lagged Honoraria Payments	-0.0001	0.0011	0.9111
Year Indicators			
2018	78.8816	12.5040	<.0001
2019	-1.2891	13.8316	0.9259

Notes:
[1] Physician fixed effects are applied to both regressions to account for unobserved physician charateristics that are constant over time. Robust standard errors clustered at physician level are used.
[2] Lagged honoraria payments are defined as Viread or Vemlidy honoraria payments in the previous year.

Source:
[1] Corrected Expert Report of Joel W. Hay, PhD, May 9, 2021 and associated production materials.

Exhibit 4
Dr. Hay's Alleged "Sham" Speaker Program Damages Summary
2013 - 2019

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Programs: 3,004	Total Claims: 48,163	Total Damages: $44,913,418	
Relators' Description of "Sham" Event Category	**Unique Program Count[1]**	**Claims Associated with Category Programs**	**Damages Associated with Category Programs[1]**	**Objective Issues Associated with Event Identification**
Programs at which the average cost of a meal was over $65 per person	2,656	41,814	$38,773,095	Includes events where the meal spend was <$65 per person
Programs at which at least one non-medical attendee was present	2,176	35,232	$32,760,412	No information provided on how medical vs. non-medical attendees identified
Programs at which more than 25% of those in attendance were non-prescribers	1,418	23,601	$22,200,026	No information provided on how medical vs. non-medical attendees identified
Programs at which a speaker was in attendance after having served as a paid speaker	703	10,756	$9,539,986	Misidentification of different people as the same person; criteria do not align with BCM
Programs at which three or fewer prescribers were in attendance	538	4,779	$4,506,536	No information on how prescribers vs. non-prescribers identified
Programs where one of the attendees had already attended at least two similar programs that calendar year	317	5,463	$5,059,912	Misidentification of different people as the same person; inclusion of Gilead personnel as repeat attendees; criteria do not align with BCM
Programs at which the members of a so-called "pod" of attendees (a group of five or more who regularly attended programs together) were present	94	3,070	$2,753,658	Inclusion of programs where no or very few "pod" members were in attendance
Programs at which a non-medical spouse or partner of a speaker or attendee was in attendance	5	52	$26,902	No information provided on how spouses were identified

Notes:
[1] Programs may fall under multiple "sham" program categories. As a result, the sum of values in the "Unique Program Count" column exceeds the "Total Programs" reported in the top row. Similarly, the impact of removing an individual event category may not reduce damages by the full amount reported in the "Damages Associated with Category Programs" field. I reserve the right to calculate alternatives damages estimations should the Court determine any particular combination of "sham" categories accurately identifies kickbacks to the paid speaker.
[2] Two programs included by Dr. Hay in his "sham" speaker program damages approach are not included in the Interrogatory Exhibits provided by Relators' Counsel. These two programs are not included in any categories above but are accounted for in Dr. Hay's overall damages total and the total unique program count.

Sources:
[1] CMS Medicare Part D Prescription Drug Event Data.
[2] CMS Medicaid claims data.
[3] Tricare data.
[4] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.
[5] Plaintiff-Relators' Objections and Supplemental Response to Interrogatories 2,5,9, and 10 of Defendant's First set of Interrogatories, May 12, 2021.

Exhibit 5
Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Claims: 48,163	Total Damages: $44,913,418
Description of Adjustment	**Claims Associated with Adjustment**	**Damages Associated with Adjustment**
Exclude unbranded programs	7,540	$6,725,265
Exclude in-office programs	2,405	$2,236,533
Exclude community programs	304	$268,334
Exclude programs with zero total honoraria	29	$26,208
Exclude patients initiated on Viread or Vemlidy by non-speaker	5,476	$5,082,899
Exclude patients initiated on Viread or Vemlidy by speaker prior to any "sham" payments	13,766	$11,906,754
Cumulative impact of adjustments	**23,572**	**$21,165,087**
Remaining alleged speaker program damages	**24,591**	**$23,748,331**

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following Advisory Board Programs):	Total Claims: 8,384	Total Damages: $7,779,434
Exclude patients initiated on Viread or Vemlidy by non-speaker	1,367	$1,294,686
Exclude patients initiated on Viread or Vemlidy by speaker prior to any "sham" payments	4,093	$3,709,270
Cumulative impact of adjustments	**5,174**	**$4,676,443**
Remaining alleged advisory board program damages	**3,210**	**$3,102,990**

Notes and sources on the following page.

Exhibit 5
Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Note:
[1] Programs and claims may meet multiple adjustment criteria. The sum of values in the "claims associated with adjustment" and "damages associated with adjustment" columns thus exceed the total values reported in the cumulative row.

Sources:
[1] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[2] Advisory Board Spend Reports (Gilead_Purcell_00134580, 00216563, 00311268, 00327017).
[3] CMS Medicare Part D Prescription Drug Event Data.
[4] CMS Medicaid claims data.
[5] Tricare data.
[6] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.

Exhibit 6
Cumulative Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Claims: 48,163	Total Damages: $44,913,418
Description of Adjustment	**Claims Associated with Adjustment**	**Damages Associated with Adjustment**
Adjustments associated with incorrectly included claims (per Exhibit 5)	23,572	$21,165,087
Account for cost of alternative treatments[2][3]	*N/A*	$30,624,412
Cumulative impact of adjustments	**23,572**	**$34,650,796**
Remaining alleged "sham" speaker program damages	**24,591**	**$10,262,622**
Account for rebates paid to Medicaid[4]	*N/A*	$459,386

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following Advisory Board Programs):	Total Claims: 8,384	Total Damages: $7,779,434
Adjustments associated with incorrectly included claims (per Exhibit 5)	5,174	$4,676,443
Account for cost of alternative treatments[2][3]	*N/A*	$6,074,367
Cumulative impact of adjustments	**5,174**	**$6,732,891**
Remaining alleged advisory board program damages	**3,210**	**$1,046,542**
Account for rebates paid to Medicaid[4]	*N/A*	$295,681

Notes and sources on the following page.

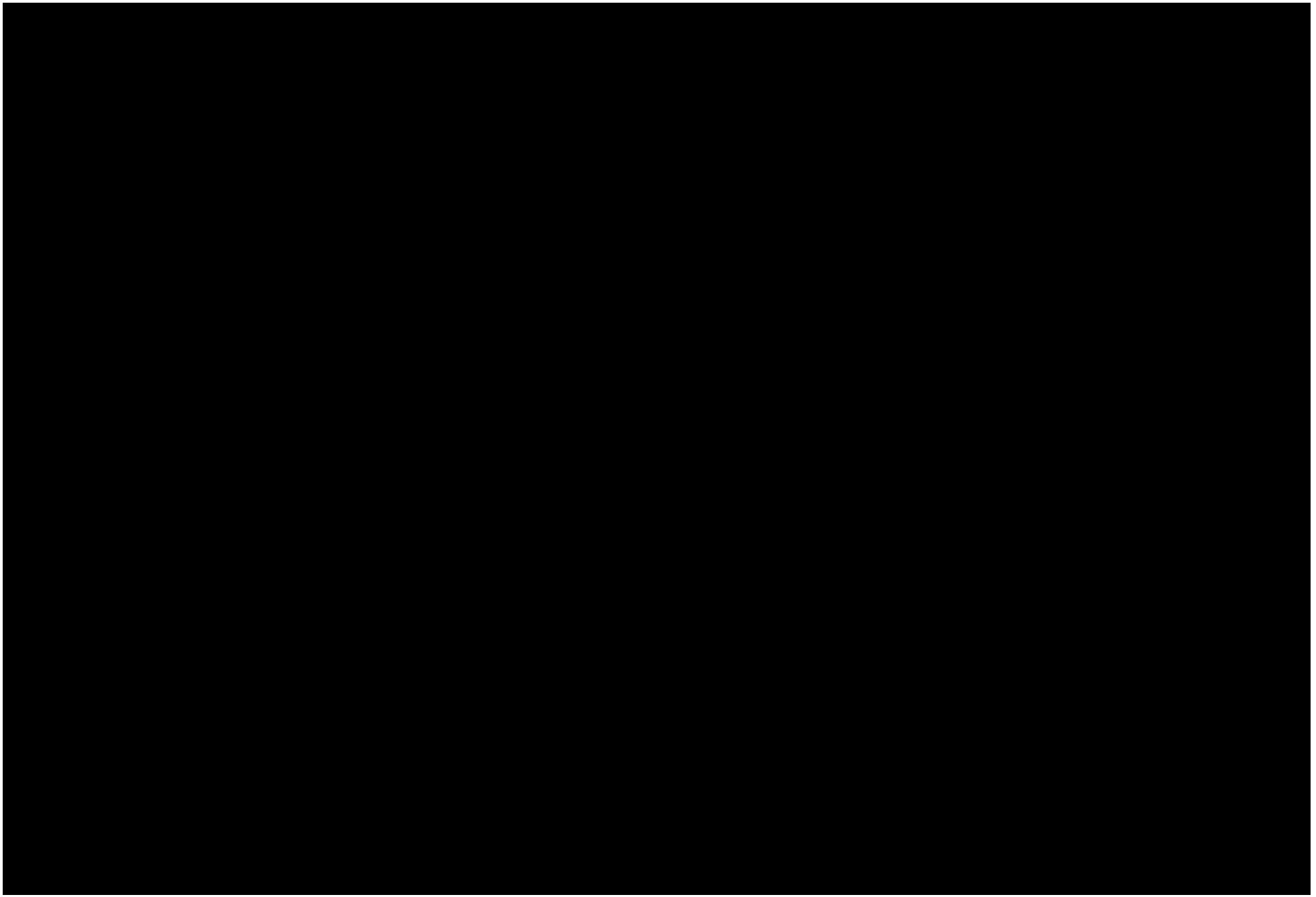
Exhibit 6
Cumulative Adjustments to Dr. Hay's 3-month Damages Calculations
2013 - 2019

Notes:
[1] Programs and claims may meet multiple adjustment criteria. The sum of values in the "claims associated with adjustment" and "damages associated with adjustment" columns thus exceed the total values reported in the cumulative row.
[2] The cost of alternative treatments is based on the paid amounts for other HBV antiviral medications. The costs are calculated annually and separately for each payor, normalized to a 30-day supply, and weighted by days-supply and non-Gilead HBV antiviral share (based on volume shares from the Symphony Health Data). The Tricare data do not include costs associated with non-Gilead HBV antiviral products and thus these costs are estimated based on the minimum Medicare or Medicaid (i.e., conservative) alternative cost in each year. To do this, I first calculate the Medicare and Medicaid alternative cost as a percentage of the combined cost of Viread and Vemlidy, respectively. Next, I take the minimum between these two percentages and multiply by the combined Tricare cost of Viread and Vemlidy in each year.
[3] Alternative HBV treatments include Baraclude and its generic formulation, Epivir HBV and its generic formulation, Hepsera and its generic formulation, Tyzeka, and the generic formulation of Viread.
[4] The Medicaid rebate percentage is calculated as the product of the weighted average unit rebate amount (total "Line Payment Amount" divided by total "Paid Units") from the Gilead Medicaid Rebate Data and total "Days Supply" in the Medicaid Claims Data, divided by the total amount paid ("MDCD PD AMT") in the Medicaid Claims Data by year and drug To account for differences between days supply and units, I only included tablet formulations of Viread and Vemlidy in both the rebate data and Medicaid claims data, and considered a 30 day supply to be the equivalent of 30 units. Rebates are not accounted for in the cumulative adjustment shown here.

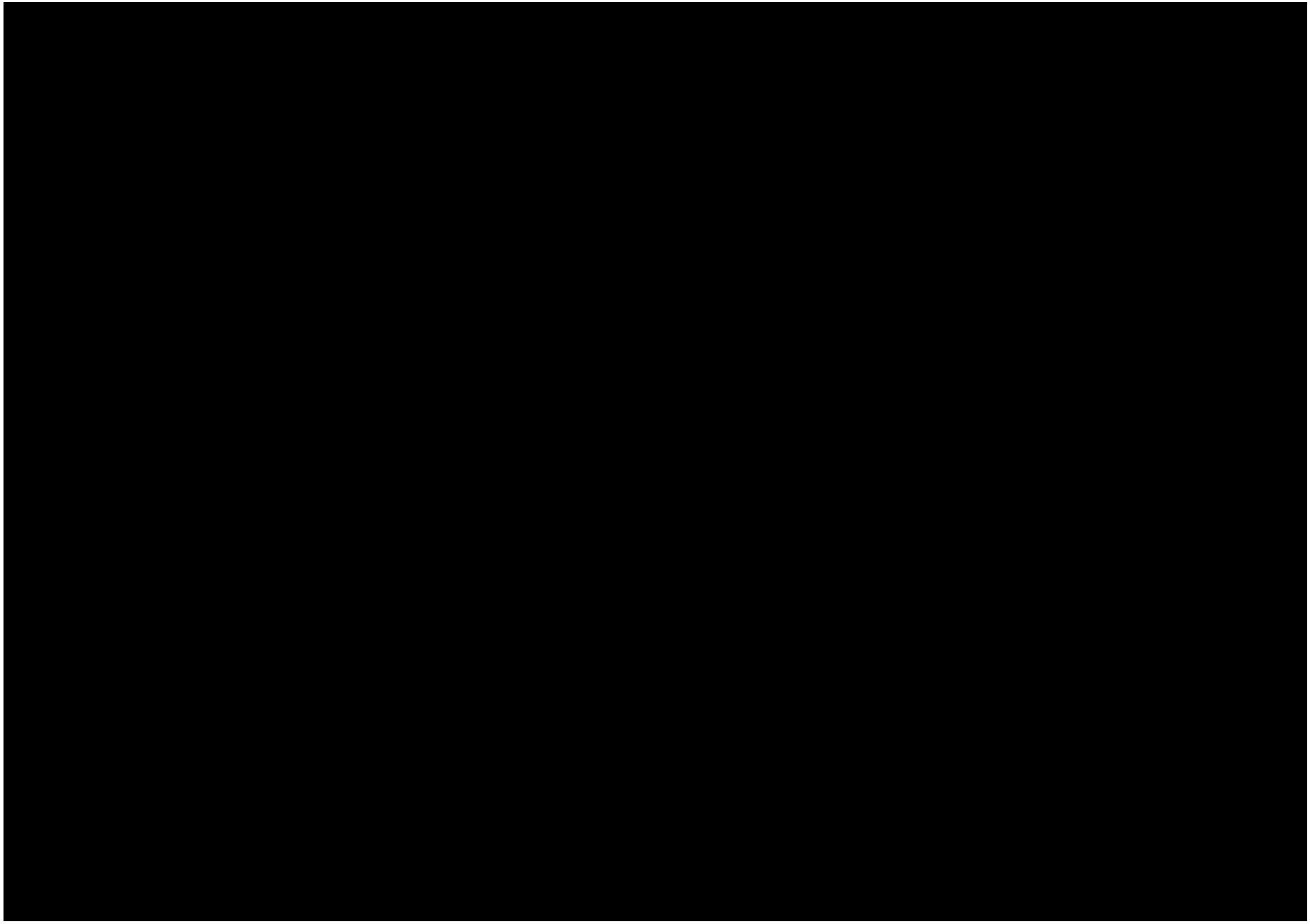
Sources:
[1] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[2] Advisory Board Spend Reports (Gilead_Purcell_00134580, 00216563, 00311268, 00327017).
[3] CMS Medicare Part D Prescription Drug Event Data.
[4] CMS Medicaid claims data.
[5] Tricare data.
[6] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.
[7] Symphony Health Data (accessed on March 18, 2021).
[8] Gilead Medicaid Rebate Data (Gilead_Purcell_00341126).
[9] IBM Micromedex Red Book Online, available at https://www.micromedexsolutions.com/micromedex2/librarian/.

Appendix 1

Events Flagged by Relators' Counsel as Greater than $65 Attendee Spend that Have Under $65 Attendee Spend

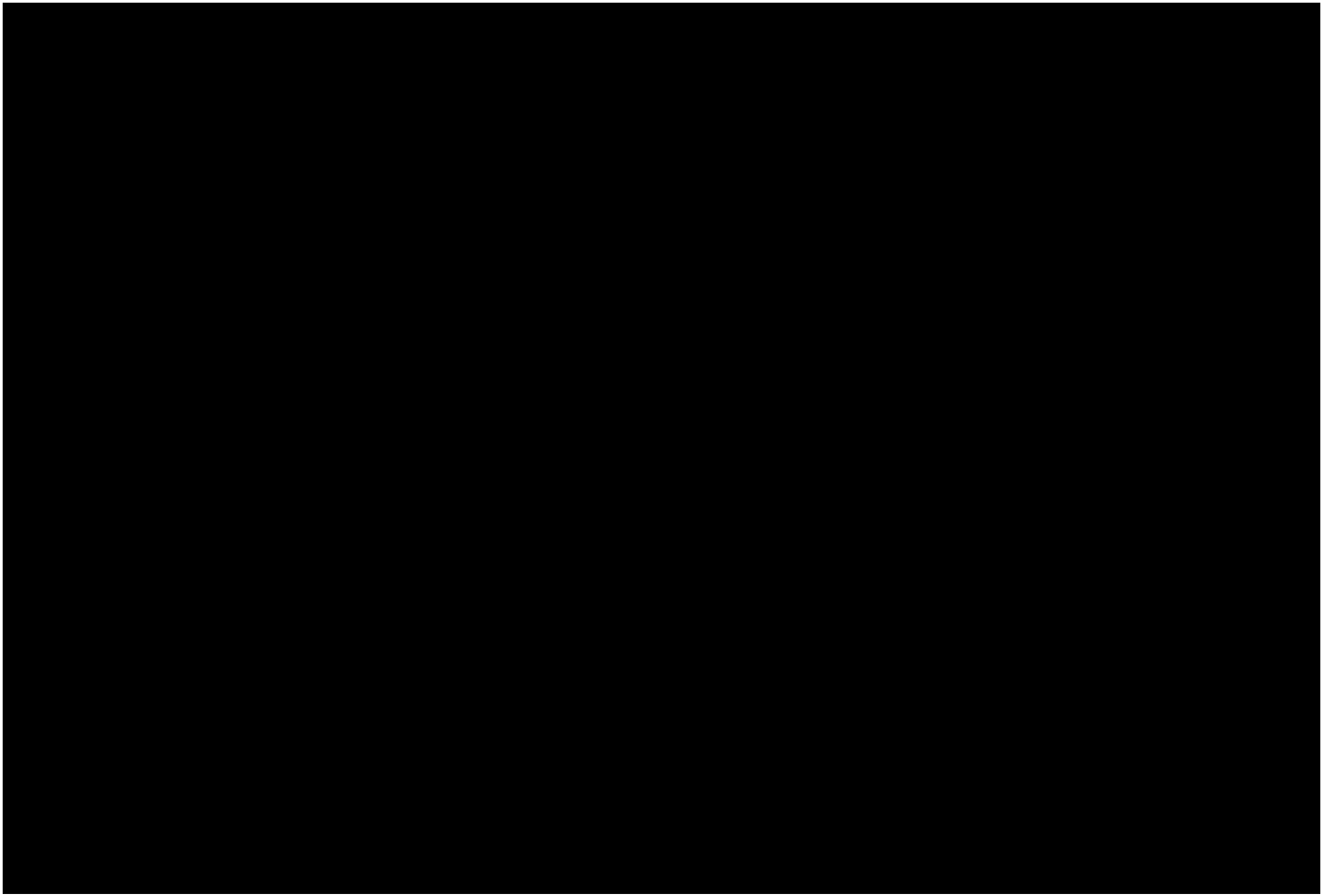


Appendix 1
Events Flagged by Relators' Counsel as Greater than $65 Attendee Spend that Have Under $65 Attendee Spend

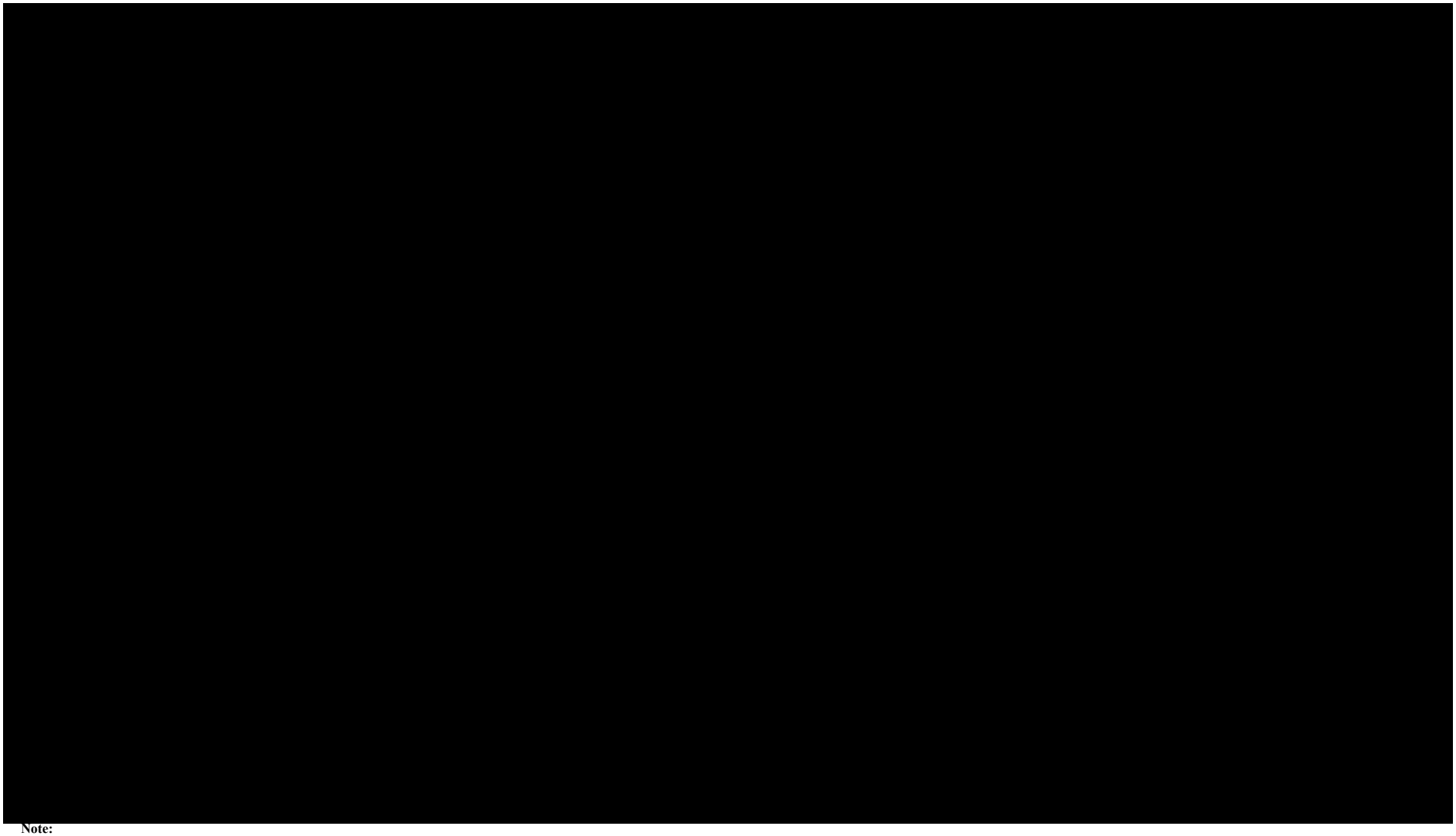


Appendix 1

Events Flagged by Relators' Counsel as Greater than $65 Attendee Spend that Have Under $65 Attendee Spend



Appendix 1
Events Flagged by Relators' Counsel as Greater than $65 Attendee Spend that Have Under $65 Attendee Spend



Note:
[1] Attendee spend is determined using AHM Attendee Spend Data

Source:
[1] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015)

Appendix 2
Annual Alleged "Sham" Speaker Program Damages Following Adjustments to Dr. Hay's 3-month Calculation

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following "Sham" Speaker Programs):	Total Damages:	Total Claims:	Total Estimated Patients[1]:
	$44,913,418	48,163	4,032

Year	Remaining Damages	Remaining Claim Count	Estimated Remaining Patient Count[1]
2013	-$122,470	625	209
2014	-$248,294	1,376	342
2015	$37,202	2,505	539
2016	$533,319	2,881	669
2017	$2,262,789	6,096	1,357
2018	$2,789,926	5,121	1,193
2019	$5,010,150	5,987	1,269
Total	**$10,262,622**	**24,591**	**2,625**

Notes:
[1] Patient identifiers are not available in the Tricare data. To estimate at-issue Tricare patients, I divide total Tricare claims by average claims per patient from Medicare.
[2] Patients appear in the Medicare and Medicaid data in multiple years. As a result, the patient count in the 'Total' row is not equal to the sum of patients in each year.

Sources:
[1] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[2] Advisory Board Spend Reports (Gilead_Purcell_00134580, 00216563, 00311268, 00327017).
[3] CMS Medicare Part D Prescription Drug Event Data.
[4] CMS Medicaid claims data.
[5] Tricare data.
[6] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.
[7] Symphony Health Data (accessed on March 18, 2021).
[8] IBM Micromedex Red Book Online, available at https://www micromedexsolutions.com/micromedex2/librarian/.

Appendix 3
Annual Alleged Advisory Board Program Damages Following Adjustments to Dr. Hay's 3-month Calculation

Dr. Hay's Viread and Vemlidy Damages (3-Months Claims Following Advisory Board Programs):	Total Damages:	Total Claims:	Total Estimated Patients[1]:
	$7,779,434	8,384	2,169

Year	Remaining Damages	Remaining Claim Count	Estimated Remaining Patient Count[1]
2013	-$7,896	95	58
2014	-$31,016	220	88
2015	-$8,275	273	95
2016	$138,339	532	182
2017	$641,612	1,639	620
2018	$220,849	347	221
2019	$92,930	104	45
Total	**$1,046,542**	**3,210**	**913**

Notes:
[1] Patient identifiers are not available in the Tricare data. To estimate at-issue Tricare patients, I divide total Tricare claims by average claims per patient from Medicare.
[2] Patients appear in the Medicare and Medicaid data in multiple years. As a result, the patient count in the 'Total' row is not equal to the sum of patients in each year.

Sources:
[1] Speaker Program Spend Reports (Gilead_Purcell_00278464, 00134582, 00324518, 00327015).
[2] Advisory Board Spend Reports (Gilead_Purcell_00134580, 00216563, 00311268, 00327017).
[3] CMS Medicare Part D Prescription Drug Event Data.
[4] CMS Medicaid claims data.
[5] Tricare data.
[6] Corrected Expert Report of Joel W. Hay, PhD., May 9, 2021 and associated production materials.
[7] Symphony Health Data (accessed on March 18, 2021).
[8] IBM Micromedex Red Book Online, available at https://www micromedexsolutions.com/micromedex2/librarian/.